DOCUMENT RESUME

ED 301 805 CG 021 293

TITLE	Infertility: Medical and Social Choices.
INSTITUTION	Congress of the U.S., Washington, D.C. Office of Technology Assessment.
REPORT NO	OTA-BA-358
PUB DATE	May 88
NOTE	412p.
AVAILABLE FROM	Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (Stock No. 052-003-01091-7, $16.00).
PUB TYPE	Reports - General (140)
EDRS PRICE	MF01/PC17 Plus Postage.
DESCRIPTORS	Constitutional Law; Ethics; Federal Legislation; *Government Role; Legal Problems; Medical Services; *Pregnancy; Prevention; *Public Policy; Reproduction (Biology); *Veterans
IDENTIFIERS	*Infertility

ABSTRACT

This report illustrates a range of options for Congressional action in nine principal areas of public policy related to infertility: (1) collecting data on reproductive health; (2) preventing infertility; (3) information to inform and protect consumers; (4) providing access to infertility services; (5) reproductive health of veterans; (6) transfer of human eggs, sperm, and embryos; (7) recordkeeping; (8) surrogate motherhood; and (9) reproductive research. After introductory chapters on infertility and the demography of infertility, full chapters are devoted to factors contributing to infertility, prevention, diagnosis, treatment, services and costs. Quality assurance for research and clinical care is discussed. Reproductive health of veterans is discussed, including factors specific to veterans, Post-Traumatic Stress Disorder, Agent Orange, and radiation. Ethical considerations relevant to infertility are reviewed, including the right to reproduce, the moral status of the embryo, and research initiatives. Constitutional considerations are described, focusing on freedom to procreate and restrictions on this freedom. The report concludes with discussions of the legal considerations of artificial insemination, in vitro fertilization, embryo transfer, gamete intrafallopian transfer, and surrogate motherhood. Among the 10 appendices are a glossary of terms, and discussions of religious perspectives, fetal research laws possibly affecting in vitro fertilization, and feminist views on reproductive technologies. (ABL)

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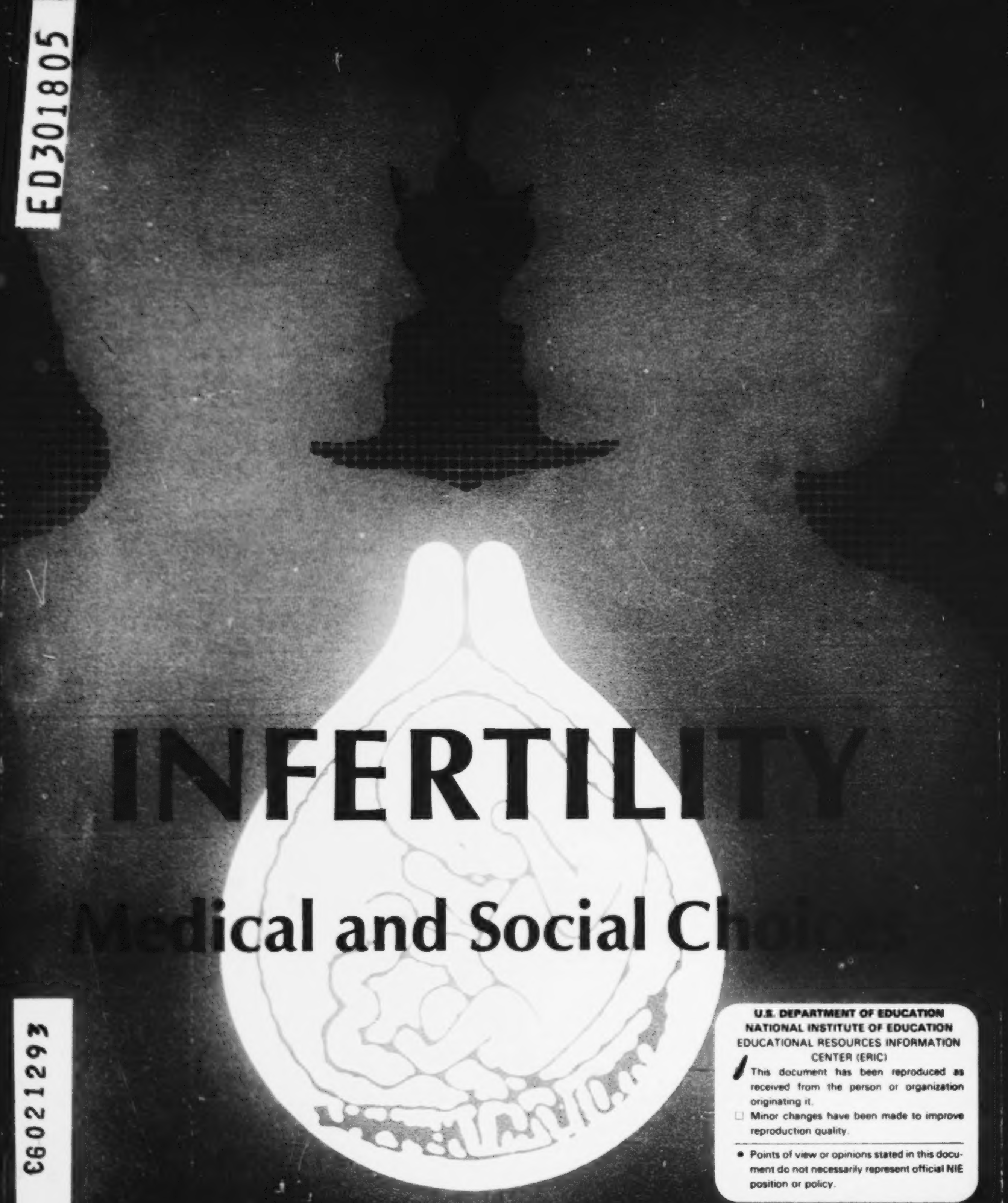

INFERTILITY

Medical and Social Choices

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INFERTILITY

Medical and Social Choices

CONGRESS OF THE UNITED STATES OFFICE OF TECHNOLOGY ASSESSMENT

Recommended Citation:

U.S. Congress, Office of Technology Assessment, *Infertility: Medical and Social Choices*, OTA-BA-358 (Washington, DC: U.S. Government Printing Office, May 1988).

Library of Congress Catalog Card Number 87-619894

For sale by the Superintendent of Documents
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Foreword

From the 1978 birth of Louise Brown, conceived through in vitro fertilization, through last year's *Baby M* case on surrogate motherhood, much attention has focused on new options available to help infertile couples form a family. Still, most infertile couples who seek help are treated with conventional drug therapy or surgery. In this assessment, OTA analyzes the scientific, economic, legal, and ethical considerations involved in both conventional and novel reproductive technologies.

The report was requested by the Senate Committee on Veterans' Affairs and the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Operations. It illustrates a range of options for congressional action in nine principal areas of public policy related to infertility:

- collecting data on reproductive health;
- preventing infertility;
- information to inform and protect consumers;
- providing access to infertility services;
- reproductive health of veterans;
- transfer of human eggs, sperm, and embryos;
- recordkeeping;
- surrogate motherhood; and
- reproductive research.

In gathering information for this study, OTA staff made site visits to 10 in vitro fertilization clinics, three sperm banks, two Veterans' Administration hospitals, and one large private medical practice that provides infertility treatment not involving novel reproductive technologies. The site visits were made in California, Louisiana, Maryland, New York, Texas, Virginia, Washington, and Australia.

OTA was assisted in preparing this study by a panel of advisors and reviewers selected for their expertise and diverse points of view on the issues covered in the assessment. Advisory panelists and reviewers were drawn from medicine, academia, the pharmaceutical industry, professional societies, religious groups, family planning groups, Federal agencies, and infertile couples. Written comments were received from 72 reviewers on the penultimate draft of the assessment. Comments on an appendix describing events in 43 foreign nations were received from an additional 60 reviewers.

OTA gratefully acknowledges the contribution of each of these individuals. As with all OTA reports, responsibility for the content is OTA's alone.

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NOTE: OTA appreciates and is grateful for the valuable assistance and thoughtful critiques provided by the advisory panel members. The panel does not, however, necessarily approve, disapprove, or endorse this report. OTA assumes full responsibility for the report and the accuracy of its contents.

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Chapter 1

Summary, Policy Issues, and Options for Congressional Action

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Chapter 1

Summary, Policy Issues, and Options for Congressional Action

This report is about the estimated 2 million to 3 million American couples who want to have a baby, but who either need medical help to do so or will remain frustrated in their desire.

In response to requests from the Senate Committee on Veterans' Affairs and the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Operations, this assessment presents the scientific, legal, economic, and ethical issues surrounding infertility. Specifically, it assesses medically assisted conception, surgically assisted conception—including in vitro fertilization (IVF) and gamete intrafallopian transfer (GIFT)—artificial insemination, basic research supporting reproductive technologies, and surrogate motherhood.

It is important to note that infertility is not only a personal medical problem, but also in some ways a social construct. It is in part a manifestation of the American commitment to a complex, pluralistic society, in which childbearing is balanced, for example, with education or career goals. This study does not examine reasons, for example, why a couple may postpone forming a family. Instead, it is limited to technologies that help establish a pregnancy. Certain allied issues, such as management of pregnancy, prenatal diagnosis including embryo biopsy, termination of pregnancy, fetal research, child health, adoption, and alternate family arrangements involving child sharing, are also beyond the scope of this report.

HOW BIG A PROBLEM IS INFERTILITY?

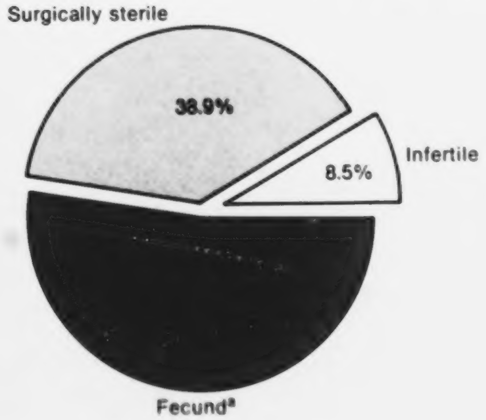
Infertility, generally defined as the inability of a couple to conceive after 12 months of intercourse without contraception, affects an estimated 2.4 million married couples (data from 1982) and an unknown number of would-be parents among unmarried couples and singles. It is an important personal and societal problem:

- Diagnosis and treatment are costly, time-consuming, intrusive, and carry about an even chance of failure.
- Avenues for prevention of infertility are uncertain.
- The substantial number of involuntarily childless people hinders the development of families, long regarded as the backbone of American society.
- Sexual behavior for both partners experiencing the stress of infertility may change radically and induce marital strife.
- Involuntarily childless couples may have to contend with family disharmony in addition to their personal disappointment.
- Infertility is often an unexpected disappointment, affecting an individual's perception of self and place in the larger scheme of generations backward and forward in time.
- Infertility frustrates one of the most basic human desires—that is, to have children.

The sole reliable sources of demographic information about infertility in the United States are national surveys conducted by the National Center for Health Statistics (NCHS). The most recent was conducted in 1982; a new survey began in 1988, and data will be available in 1989. **In 1982, an estimated 8.5 percent of married couples with wives aged 15 to 44 were infertile**, 38.9 percent were surgically sterile, and 52.6 percent were fertile, or more precisely, fecund (see figure 1-1). It is important to note that surgical sterilization masks some couples who were infertile anyway. (If those who were surgically sterile are excluded from the population base, the 2.4 million couples account for 13.9 percent of the remaining 17.3 million couples.) **Infertility generally increases with age** (see figure 1-2).

Figure 1-1.—Infertility in the United States, 1982

Married couples, 15-44 years



[a] Potentially able to conceive.

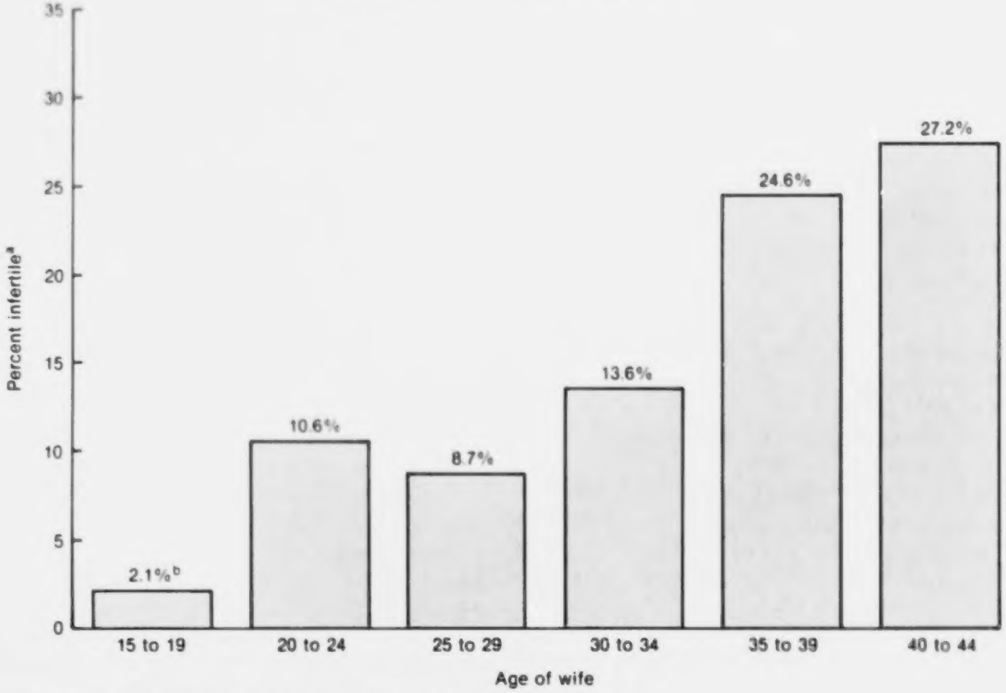
SOURCE: Office of Technology Assessment, 1988

The overall incidence of infertility remained relatively unchanged between 1965 and 1982 (see figure 1-3). **One age group, married couples with wives age 20 to 24, exhibited an increase in infertility (from 3.6 percent infertile in 1965 to 10.6 percent infertile in 1982).** This increase may be linked to the rate of gonorrhea in this age group—a rate that tripled between 1960 and 1977.

Childlessness, or primary infertility, has increased and affects about 1.0 million couples. Secondary infertility (in which couples have at least one biological child) has decreased and affects about 1.4 million couples. Surgical sterilization has increased dramatically (see figure 1-4). Certain couples are more likely than others to be infertile: The incidence among blacks, for example, is 1.5 times higher than among whites.

It is noteworthy that not all infertile couples seek treatment. An estimated 51 percent of couples with primary infertility and 22 percent with secondary infertility seek treatment.

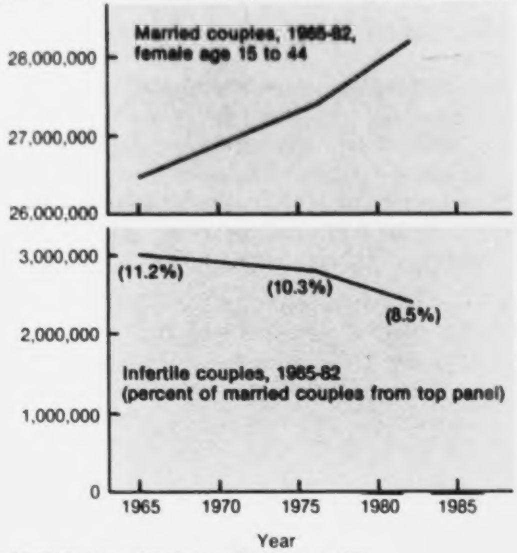
Figure 1-2.—Infertility and Age, 1982



[a] Percent of married couples, excluding those surgically sterilized, who are infertile.
[b] Likely an underestimate because married teenagers have not yet had time to discover that they are infertile.

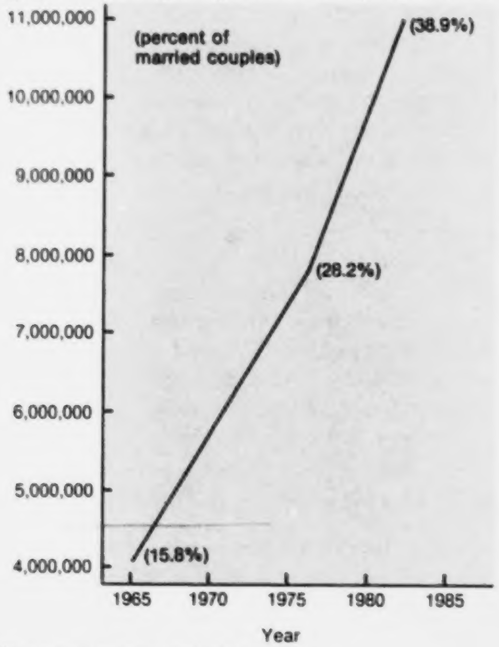
SOURCE: Adapted from W.D. Mosher, "Infertility: Why Business is Booming," *American Demographics* 9:42-43, 1987.

Figure 1-3.—Married Couples and Infertility, 1965-82



SOURCE: Office of Technology Assessment, 1988.

Figure 1-4.—Surgically Sterile Couples,ª 1965-82

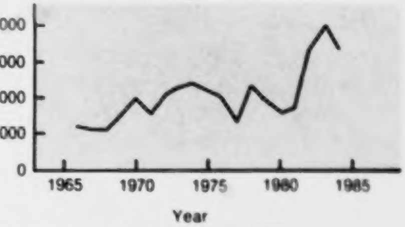


ªOne or both partners surgically sterilized.

SOURCE: Office of Technology Assessment, 1988.

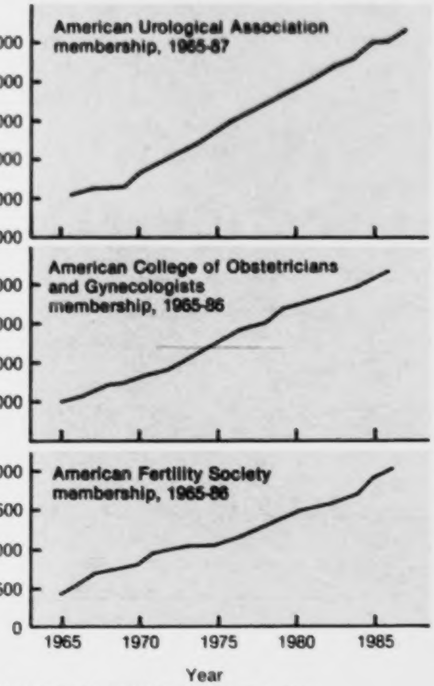
Although there has been no increase in either the number of infertile couples or the overall incidence of infertility in the population, the number of office visits to physicians for infertility services rose from about 600,000 in 1968 to about 1.6 million in 1984 (see figure 1-5). Concomitant increases occurred in the memberships of the American College of Obstetricians and Gynecologists, the American Fertility Society (AFS), and the American Urological Association, the three chief professional organizations for physicians who treat infertile patients (see figure 1-6).

Figure 1-5.—Physician Office Visits for Infertility, 1966-84



SOURCE: Office of Technology Assessment, 1988.

Figure 1-6.—Membership in Infertility Professional Organizations, 1965-86



SOURCE: Office of Technology Assessment, 1988.

WHAT FACTORS CONTRIBUTE TO INFERTILITY, AND CAN IT BE PREVENTED?

Three factors most often contribute to infertility among women: problems in ovulation, blocked or scarred fallopian tubes, and endometriosis (the presence in the lower abdomen of tissue from the uterine lining). Infections with sexually transmitted diseases (STDs), principally chlamydia and gonorrhea, are an important cause of damaged fallopian tubes. **Among men, most cases of infertility are a consequence of abnormal or too few sperm.** For as many as one in five infertile couples, a cause is never found.

Preventing infertility is difficult. Factors that contribute to abnormal or too few sperm, for example, are largely unknown. Other factors, like endometriosis, are not amenable to prevention. Nevertheless, prevention strategies are desirable, because they may help some couples avoid the considerable emotional and economic costs associated with infertility treatment, and they may preempt some infertility that would be wholly untreatable.

Infertility resulting from sexually transmitted diseases—an estimated 20 percent of the cases in the United States—is the most preventable. In these instances, prevention of infertility equals prevention (and rapid and effective treatment) of sexually transmitted diseases. The risk of infertility increases with the number of times a person has chlamydia or gonorrhea, the duration and severity of each infection, and any delay in instituting treatment.

Effective public health initiatives aimed at preventing STDs and infertility include efforts in the following areas:

- health education of patients and public health professionals;
- disease definition, including long-term sequelae of STDs;
- optimal treatment and improved clinical service;
- partner tracing and patient counseling; and
- research, including the social, psychological, and biologic aspects of STDs.

It is noteworthy that changes in sexual behavior, attitudes about discussing sex, and health education wrought by the epidemic of acquired immunodeficiency syndrome (AIDS) could have the salutary effect of preventing some infertility due to STDs.

The calculus of infertility includes the age of the prospective mother. The probability of infertility increases somewhat after age 30 and significantly more after age 35. Although no one social prescription fits all couples in all circumstances seeking to conceive, biology dictates that to maximize the chance of natural conception, a couple should maximize the number of months or years devoted to attempting it. A woman's reproductive lifespan is circumscribed, and whenever the decision to procreate is made, the chance of success generally depends on the number of months during which conception is attempted. **The probability of conception is reduced both by delaying childbearing and by condensing attempts into a relatively short time period.**

A promising area of research in prevention is the identification of behavioral, physiological, and environmental risk factors for infertility. One goal of such research is to help young adults take measures to preserve their future fertility. Table 1-1 summarizes preventive approaches for some known and hypothesized risk factors for infertility.

HOW IS INFERTILITY DIAGNOSED AND TREATED?

Infertile patients obtain care from an estimated 45,600 physicians: 20,600 obstetrician-gynecologists, 17,500 general or family practitioners, 6,100 urologists, and 1,400 surgeons. Sophisticated or innovative procedures for treating infertility cases are most likely to be available in urban areas and at university medical centers.

Fertility is the product of interaction between two people and so the infertile *patient* is in effect the infertile *couple*. Examination of the male is simplified by the fact that his reproductive organs and sperm are readily accessible. This accessibility is not, however, accompanied by better and more varied treatments for the male.

Table 1-1.—Prevention of Infertility

Factors predisposing individuals toward infertility and preventive steps available

Sexually transmitted diseases (STDs) and pelvic inflammatory disease (PID):
- Careful selection of possible sexual partners. Health education to discourage unprotected sexual encounters. Monogamy. Forthright inquiry and check of sexual partners for risks of STDs.
- Contraception by means of condoms. Use condoms routinely with new sex partner. Media campaign to encourage condom use.
- Periodic screening for STDs, if sexually active; STDs in both males and females are commonly asymptomatic.
- Changes in societal attitudes about STDs to lessen stigma of diagnostic examination for them.
- Recognize findings of STDs and seek medical care. Ensure that correct treatment is given for yourself and partner, with followup.
- Media campaign to encourage men and women with genital discharge to be checked for STDs.
- Rapid, adequate management of PID to reduce risk of sequelae.

Pelvic infections after birth, abortion, surgery, or invasive diagnostic testing:
- Ensure that optimally safe birth and surgical services are available.
- Use prophylactic antibiotics in high-risk situations to prevent infection.

Exercise, poor nutrition, and stress:
- Recognize that regular strenuous exercise (i.e., exceeding 60 minutes daily), rapid weight loss, low body fat, and stress may cause decreased fertility. Women are at higher risk than men.

Smoking, environmental toxins, and drugs:
- Smoking, as well as other substance abuse, reduces reproductive potential and should be avoided. Environmental exposures are inadequately studied, but appear more common in males. Semen analysis can be performed.

Endometriosis:
- If strong family history for endometriosis exists, consider oral contraception and possible specific endometriosis suppression. Oral contraceptives may suppress endometriosis even in those not at high risk.
- Early diagnosis and treatment in symptomatic women. Conservative surgical approaches.

Cryptorchidism and varicocele:
- Undescended, especially intra-abdominal, testes should be treated as promptly as possible. Benefits of surveillance and treatment of varicocele are controversial.

Chemotherapy and radiation:
- Risks of gonadal damage must be considered and, if appropriate, gamete collection or protection of the gonads should be performed.

Intercurrent illnesses:
- Many acute and chronic diseases cause anovulation or decreased spermatogenesis. Prevention of these effects is by treatment of the primary disease.

Inadequate knowledge of reproduction:
- Ensure that information on reproduction is available from parents, schools, clergy, and other sources.

Inadequate medical treatment:
- Couples with difficulty conceiving should educate themselves about fertility and seek specialized care before infertility is prolonged.

Lack of perspective about reproduction:
- Discuss family life with parents, peers, and professionals. Formulate life plan that allows adequate time for reproductive goals.

SOURCE: Office of Technology Assessment, 1988.

This is due, in part, to a continued lack of knowledge about male reproductive physiology. Female reproductive health can be estimated through a variety of indirect indicators (e.g., menstrual regularity, hormone levels, properties of cervical mucus) and direct methods (e.g., tissue biopsy, laparoscopy, ultrasound imaging). Even with sophisticated diagnostic technology, however, no fertility test can positively predict a woman's ability to conceive or maintain a pregnancy.

Among infertile couples seeking treatment, 85 to 90 percent are treated with conventional medical and surgical therapy. Medical treatment ranges from instructing the couple in the relatively simple methods of pinpointing ovulation to more complex treatments involving ovulation induction with powerful fertility drugs and artificial insemination. Surgical treatments also span a wide spectrum of complexity, ranging from ligation of testicular veins for eliminating varicocele to delicate microsurgical repair of reproductive tract structures in both men and women. Beyond being physically invasive, treatment is often emotionally taxing (see box 1-A). Ovulation induction, surgery, and artificial insemination are the most widespread and successful approaches to overcoming infertility.

Two noncoital reproductive technologies—IVF and gamete intrafallopian transfer (GIFT)—offer hope to as many as 10 to 15 percent of the infertile couples who could not be successfully treated otherwise. These techniques are being practiced with increasing frequency, but proficiency varies widely. Some 70 to 80 medical teams in the United States have established a record of some success with IVF, and proficiency with GIFT is increasing. However, the remainder of the 169 IVF/GIFT programs in this country have had little or no success to date.

Counseling is an important and often underutilized component of infertility treatment.

Box 1-A.—Infertility's Emotional Toll

Crazy Feelings Are Normal

You are sitting in the waiting room of your doctor's office. You have been trying to have a baby for 3 years and things are not happening the way you had planned. You have been on clomiphene for a year. Lately you cry at the drop of a hat—when you see a diaper commercial on television, see a pregnant woman at the grocery store, or get an invitation to a baby shower. The whole world seems to be having babies.

You always thought of yourself as competent, able to handle anything. Now you feel depressed every month when your period begins. You are beginning to think that having a baby is the only thing that will make your life worthwhile. You feel odd, different. *Everyone* can have a baby. *What's wrong with me?* You may start to wonder if you are getting a little crazy.

You find yourself experiencing feelings that you have never had before. Sometimes you are depressed when you never used to be, or you avoid situations that have anything to do with children. Over the last 6 months, the entries in your private diary include:

I must have done something wrong to deserve this.
I have to keep an important part of my life secret.
I have nobody I can talk to about this.
Sex on schedule takes all the joy out of making love.
Nobody understands how I feel, even my husband.
I'm angry all the time.
I feel as if everything in my life is on hold.
I'm always tired lately.
I've lost my self-confidence.
I feel like a failure in everything in my life.
I feel sad and alone.
I'm afraid my husband will give up on me.
We don't have fun anymore.
We don't fit in with our friends; they all seem to be into children.
My family can't support me like they used to, especially on special occasions when children are the center of attention.
If I could just stop trying so hard, maybe I could get pregnant.

Feelings of Helplessness and Responsibility

It is 2 p.m. You are sitting with your wife in the doctor's office, waiting to be told what to do next to get your wife pregnant. You gave a semen sample 2 days ago to some lab person. You are sure that humiliating experience was just the beginning of many more. You are wondering how bad your sperm are.

You think about your wife and how tense you feel when her period is due. It used to be, when you were first married and didn't yet want a baby, that you kept track of her period to make sure she wasn't pregnant. Now you are still counting days, but for the opposite reason. Times sure have changed; in the old days, you never gave infertility a thought.

You are afraid to ask how she is feeling and are ambivalent about listening to her talk about symptoms that sound like she is pregnant. You begin to get hopeful, yet worry about feeling let down when her period begins.

What if the doctor suggests a specialist, another semen sample, surgery on your testes? Don't they know how much you hate masturbating in the bathroom while they wait outside? You wonder if your wife will want to be with you if you can't give her a child. How will you explain to your family that you can't continue their name? What if your wife wants to use donor sperm? Can she possibly understand how defective and inadequate this makes you feel? The aloneness and disconnectedness is intense.

Your wife has always been your best friend, your confidant. How can you tell her how angry you feel that struggling to have this baby has created a distance between you? How can you tell her how sad you feel when she starts her period? How can you tell her how helpless you feel? How *responsible* you feel.

You stifle all that. She needs your support.

She asks if you hurt. You abbreviate your answer, thinking that it will be easier for her. You miss the old easy way you had with each other. Last week, you lashed out in a way that made it seem like you don't have any feelings about all that the two of you have been through. It only takes one sperm to impregnate an egg, so what's the big deal about the number and how well they move and what they look like? Most of all, you just hope the doctor will tell you what to do.

SOURCE: S.G. Mikesell and A. Hammond, Licensed Psychologists, Washington, DC, personal communications, Oct. 30 and Dec. 23, 1987.

Patients may derive psychological support from professional counseling at an infertility clinic, counselors in private practice, or community support groups. One nationwide support group for infertile people, Resolve, has 47 chapters nationwide.

As many as half the infertile couples seeking treatment will ultimately be unsuccessful, despite trying various avenues of treatment. Knowing when to stop treatment is an individual matter for each infertile couple. A decision often comes as couples ask themselves:

- Is further treatment worth the pain, expense, and disruption?
- Is adoption or childlessness becoming an acceptable option?
- Is treatment costing so much that other goals are sacrificed?
- If it is not yet time to stop, when will it be?

Conception is a matter of chance, and embryonic loss is a normal phenomenon in mammalian reproduction. Yet for those unable to have the child they want, infertility can be a lifelong legacy (see box 1-B).

Box 1-B.—The Lifelong Legacy of Infertility

Some infertile couples, confronted with the rather limited options by which they can enlarge their families, make the conscious choice to live their lives without children, perhaps deciding to channel their energies into work, recreation, creative endeavors, or philanthropic efforts. For some couples, this is fine. They feel their lives are full. For others, however, it is more difficult. They may worry about being the last of their genetic line. Some talk about being confronted prematurely with a sense of their own mortality.

For those who are troubled by their infertility, childlessness may disappear as a source of unhappiness during midlife, not to appear again until the late elderly years, and then as lack of an emotional and economic resource rather than as part of an identity crisis. Often the times we are most vulnerable to self-doubt are around life's milestones: retirement, menopause, or developments in the lives of family and friends, particularly those with children.

Some couples fear the isolation and loneliness of growing old alone, and from time to time they may wonder whether they will be able to handle the process of aging without an adult child or grandchildren to support them and offer company. In fact, as friends of the childless couple rejoice in births of grandchildren, the infertile couple may find that they feel social isolation emerging once again in their lives.

SOURCE: Office of Technology Assessment, 1988.

WHO ASSURES THE QUALITY OF INFERTILITY TREATMENT?

With treatments for infertility growing more sophisticated, it is increasingly important for patients to understand the realistic likelihood that these procedures will succeed, and to have reasonable assurance of quality care. Success rates among IVF clinics, for example, vary widely; nearly half have yet to achieve a live birth following IVF.

Professional societies—voluntary organizations of practitioners—such as the American Association of Tissue Banks, the American College of Obstetricians and Gynecologists, and the American Fertility Society have made efforts to regularize the practice of medically assisted conception. They have promulgated guidelines on gamete and participant screening, physician training, and clinic staffing. Compliance with such guidelines, however, is voluntary.

Couples seeking the most talked-about new reproductive technology, IVF, are often in a quandary over assessing practitioners' skills. Is IVF experimental or is it a proven medical therapy? In 1988, no blanket answer to that question is possible. Just as some physicians in IVF programs in the United States are proven practitioners of the art, others are as yet unproven.

In 1986, the American Fertility Society concluded that a procedure (e.g., IVF) done for the first time by a practitioner or for the first time at a particular facility should be viewed as experimental, implying that after some number of attempts, the procedure is no longer experimental. AFS also stated that charges should be reduced until a clinic has established itself with a reasonable success rate, implying that a reasonable success rate characterizes the clinic as no longer providing experimental treatment. These lines of reasoning leave unclear whether it is the number of times IVF has been used or the success with which it is used that determines its experimental status.

Regulation of noncoital reproductive techniques has been primarily a matter for individual States, despite avenues of Federal authority. Regulation of quality control and of monitoring, safety, recordkeeping, inspection and licensing, obligations of mothers and fathers, and requirements for sperm donor screening are well within the traditional bounds of State responsibility related to medical practice and matters of family law. Federal activity in assisted reproduction has consisted largely of supporting national commissions to study scientific, legal, and ethical issues.

HOW MUCH DOES INFERTILITY COST?

The dollar value of the personal, familial, and societal losses caused by infertility is inestimable. Americans spent, however, about $1 billion on medical care in 1987 to combat infertility. Approximately 7 percent of the total was spent on IVF. Some 14,000 attempts at IVF were performed in 1987. In other words, IVF was undertaken by less than 1 percent of the estimated number of infertile couples in the United States who sought treatment.

Costs to individual couples receiving care for infertility vary dramatically, depending on the severity of their problem and their perseverance in seeking treatment. A complete diagnostic workup typically costs $2,500 to $3,000, although most couples do not require such an extensive workup. Medical treatment may cost an additional $2,000 to $8,000; in the extreme, medical treatment may cost more than $22,000. Further, because conception is a precisely timed biological event, infertility diagnosis and treatment often involve the costs of time away from work and may involve travel and hotel costs.

Many private health insurers do not cover infertility per se or provide only limited coverage, yet in practice a substantial portion of infertility expenditures are reportedly reimbursed. Some individual procedures are covered, particularly if they are not identified as part of an overall treatment for infertility. In other instances, some physicians find disingenuous ways to invoice for infertility services, so as to obtain reimbursement from insurers for their patients. Treatment related to IVF is specifically excluded from coverage by the majority of health plans, but substantial reimbursement occurs for the various components of IVF treatment (e.g., hormonal stimulation). Subterfuge by some physicians in order to obtain reimbursement for their patients from insurers is reported to include invoicing for egg retrieval for IVF under the guise of "aspirating a trapped oocyte."

IVF patients undertake an estimated two IVF cycles on average, with most of them ceasing treatment after that for financial reasons, prior to achieving a successful pregnancy. Broader insurance coverage would likely lead to more patients attempting IVF and to more IVF attempts per patient, with consequent greater individual success. **Arkansas, Hawaii, Maryland, Massachusetts, and Texas have mandated that insurers cover IVF, although in limited fashion.**

The 3.0 million current civilian employees of the Federal Government are covered by 435 different health plans nationwide. The large, nationwide plans participating in the Federal Employees Health Benefits Plan (FEHBP) cover many traditional medical and surgical treatments for infertility, but exclude coverage of IVF, reversals of sterilization, and artificial insemination. Assuming that from 2,500 to 3,000 civilian Federal employees undertake an average of two IVF cycles each, extending insurance coverage under FEHBP for IVF would cost an estimated $25 million.

WHAT ETHICAL ISSUES ARE INVOLVED?

A wide range of conflicting established moral viewpoints makes the development of public policy related to infertility difficult. Where there are pluralities of viewpoints and a lack of any single established moral approach, uniform solutions are questionable.

Recent years have seen the appearance of several ethical analyses of reproductive technologies, with most leading to pronouncements that a particular technology is either ethically acceptable or not. In 1987, for example, the Roman Catholic Church issued its *Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation*. The Church supported basic medical and surgical treatment for infertility but opposed nearly all other techniques for diagnosing and treating infertility.

Similar analyses examine at least six themes:

- **The right to reproduce.** Procreation is seen by most as a fundamental facet of being human. Differing views about the relative importance of procreation have spawned disagreement over how to balance a claim to reproduce against other needs. Critical unanswered questions are whether infertile couples have the right to use the gametes or bodies of others, and the right to financial assistance to obtain treatment they might not otherwise be able to afford.
- **The moral status of an embryo.** IVF and the ability to freeze embryos raise questions about appropriate treatment of embryos that are likely to be debated for some time to come. While some recognize embryos as full persons from the moment of fertilization, others claim an embryo has no moral status whatsoever. Still others contend embryos have significant moral standing, although not equal to that of a person. The unresolved debate about how to view and handle human embryos has impeded the growth of new knowledge about fertility, infertility, and contraception.
- **Bonding between parent and child.** Parent-child bonding is important both to parents and to the developing personality of the child. Conception that involves the efforts of a third party may redefine parenthood. The use of reproductive technologies raises questions about the minimum requirements for bonding and the meaning of parent-child relationships—and what they ought to be.
- **Research with patients.** Infertile patients have a right to know when treatment is a proven medical therapy and when it amounts to an experimental trial. Further, because of their often intense effort to conceive, infertile patients are particularly vulnerable to abuses of the researcher-subject relationship.
- **Truth-telling and confidentiality.** The intimate nature of infertility diagnosis and treatment and the use of donor gametes complicates simple ethical imperatives to tell the truth and to hold personal information in confidence.
- **Responsibilities of one generation to another.** Parents, physicians, and researchers have a duty to refrain from using reproductive technologies in ways that might harm future generations.

Most religious traditions in the United States view necessary medical or surgical treatments for infertility as acceptable and hold them to be desirable. There is general acceptance of the morality of artificial insemination by husband, considerable hesitation about artificial insemination by donor, and even less support for artificial insemination of single women. Most religions support IVF or gamete intrafallopian transfer using the married couple's own sperm and eggs as long as no embryos are discarded. Surrogate motherhood is largely opposed in any form.

WHAT DOES THE LAW SAY?

The U.S. Constitution has been interpreted to preclude almost any kind of governmental effort to prevent competent individuals from marrying and exercising their innate fertility. Yet there is no explicit statement in the Constitution of either a right to procreate or a right to privacy. Court decisions do not clearly state whether such rights extend to a right to obtain medical services, to use donor gametes, to use a surrogate mother, or to pay for these three avenues of overcoming infertility. Nevertheless, any governmental effort to regulate or ban any aspect of noncoital reproduction is certain to be subjected to judicial scrutiny.

Issues likely to be before the courts in the coming years include regulation of medical treatments using a couple's own gametes, restrictions on use of embryos not transferred, payment for undergoing medical procedures that carry some risk (e.g., ova donation), payment for embryos and their transfer, and the government's obligation to pay for or otherwise provide infertility services for poor people.

Noncoital reproduction introduces two prominent complications into family law, traditionally the domain of the States. First, when donor gametes are used, the legal identification of a child's mother and father may come into question. A majority of States have already rearranged presumptions of legal paternity following the conception of a child by donor insemination. Some problems remain when the donor wishes to have some legal relationship with the child or when the recipient is unmarried. States have not yet begun to grapple with egg or embryo donation. These are more complicated because the gestational mother may or may not intend to raise the child. Therefore, models based on artificial insemination—which balance rearing and genetic paternity—are insufficient to cover cases requiring balancing of rearing, gestational, and genetic maternity.

Second, when extracorporeal embryos are at issue, questions arise concerning the legitimacy of actions with embryos (e.g., sale, transfer to nongenetic relations, or disposal) and, further, concerning who may make decisions concerning embryos. At least two State legislatures have considered the problems raised by extracorporeal embryos. Louisiana has tried to give them the legal status of a child—meaning, among other things, they cannot be sold or discarded—but the law has yet to face a constitutional challenge based on its possible conflict with related Supreme Court decisions.

Florida has outlawed the sale of embryos. This has not yet been challenged as an interference with the right to procreate. The question has largely been avoided as physicians have been careful to obtain the opinions and consent of the genetic parents before doing anything with an embryo. It remains unclear whether an embryo has status as the property of the genetic parents (meaning it can be disposed of as they please) or as analogous to that of a child of the genetic parents (meaning it is protected by State law from parental actions that are harmful), or some other status as yet unenunciated.

IS SURROGATE MOTHERHOOD HERE TO STAY?

Surrogate motherhood is more a social solution to infertility than it is a medical technology. It burst into American consciousness in 1987 with saturation media coverage of the *Baby M* case, when a woman changed her mind and wanted to keep the baby she bore, but was forced to yield the child to the biological father who had hired her. **The legal status of surrogate motherhood arrangements is today unsettled and likely to stay that way for some time to come.**

Surrogate motherhood may occur in two ways. A woman may be artificially inseminated with the sperm of a man who intends to be the rearing parent of the resulting child. Or a woman may be the recipient of a transferred embryo and carry to term a baby to whom she is genetically unrelated. The former procedure is far more common than the latter, although surrogacy involving embryo transfer could become more common in the future.

About 600 surrogate mother arrangements have been concluded to date. In a few of these, the participants indicated that they had either changed their intentions or been otherwise dissatisfied with the outcome. About 15 surrogate mother matching services are active in the United States, and as many as 100 surrogate mother arrangements may be concluded annually over the next several years. A typical contract involves a $10,000 fee to the surrogate mother and an additional $20,000 to $30,000 in living expenses, medical expenses, and attorneys' fees. In such a circumstance, about $1 out of every $4 actually goes to the surrogate mother. Contracts often impose restrictions on a surrogate's personal habits during pregnancy (e.g., smoking, alcohol consumption, exercise) and conditions for medical care (e.g., mandatory amniocentesis).

Legislation addressing surrogate motherhood has been introduced in more than half the State legislatures, and four States have passed laws. In 1987, Louisiana enacted legislation inhibiting surrogacy; in contrast, Arkansas has statutorily facilitated surrogate motherhood under some circumstances. Nevada exempted lawful surrogacy from its ban on baby-selling, and Kansas exempted surrogacy from prohibitions on advertising. State court decisions have consistently found surrogacy contracts to be unenforceable, even though they have split on whether the contracts are illegal.

In the absence of Federal legislation or Federal judicial decisions, State legislatures and courts are likely to continue to come to different conclusions about the desirability of commercialized surrogate motherhood.

WHAT REPRODUCTIVE HEALTH CARE DO VETERANS RECEIVE?

The Veterans' Administration (VA), the Nation's largest health care delivery system, offers only limited treatment for infertility in its 172 medical centers and 227 outpatient clinics. Since infertility treatment often involves the examination and treatment of both partners, and the VA has authority to administer medical treatment solely to veterans, the VA lacks authority to treat a nonveteran spouse of an infertile couple. Most important, **the VA does not classify infertility as a primary disability, thus severely limiting the treatment available to veterans.**

In 1985, about 16,000 male veterans and just over 1,200 female veterans had known service-connected medical conditions that could lead to infertility. ("Service-connected" refers to a disease, injury, or other physical or mental defect incurred during the time of active military service. It does not necessarily imply active combat.) Among the men, the conditions ranged from removal of the testes or prostate to spinal cord injury. Among the women, the conditions ranged from removal of the ovaries to inflammation of the fallopian tubes or cervix. The VA, however, performed few procedures related to infertility among these veterans.

Spinal cord injury, caused principally by battlefield trauma during wartime and vehicular and diving accidents during peacetime, is of special concern to both the VA (which supports 20 spinal cord injury centers) and veterans' advocacy groups. The current outlook for fertility after spinal cord injury in paraplegic men (although not women) is often poor. Erection and ejaculatory dysfunction, compounded by infections of the urogenital tract, are common. VA research on electroejaculation and vibration-induced ejaculation is likely to offer hope for fertility to veterans—and ultimately nonveterans—with spinal cord injuries. Ironically, even when sperm are obtained in this way by VA physicians, insemination of the veteran's nonveteran wife cannot be undertaken under VA auspices.

WHAT HAVE OTHER COUNTRIES DONE?

Eight other nations (Australia, Canada, Federal Republic of Germany, France, Israel, the Netherlands, Sweden, and the United Kingdom) have enacted legislation or issued major Government reports on the use of noncoital reproductive technologies. At least another 35 countries and four international organizations have had public debate, considered legislation, or examined some aspect of this issue.

Artificial insemination by husband and donor are generally considered acceptable techniques worldwide. Several countries have legislation stating that children resulting from artificial insemination by donor are the legitimate offspring of the woman and her consenting husband. IVF is generally considered acceptable, provided it is used only when medically necessary.

The use of artificial insemination and IVF by unmarried couples, homosexual couples, and single men and women is more controversial. The use of donor gametes in IVF is not universally accepted. Oocyte donation is not as widely accepted as sperm donation, largely because the technology is considered experimental. Acceptance of embryo donation varies widely.

Most controversial are the topics of surrogate motherhood and research on human embryos. Countries that do approve embryo research often stipulate that embryos must be excess ones obtained through IVF, not created for research, and they often impose a time limit after which research must end (e.g., 14 days after fertilization). Surrogate motherhood has achieved little acceptance, and several countries have taken steps to ban the practice, especially its commercial use.

WHERE DO REPRODUCTIVE TECHNOLOGIES GO FROM HERE?

Speculation about reproductive technologies yet on the horizon has captured the public's imagination like few other aspects of infertility treatment, although new reproductive technologies are only one factor driving increased interest in infertility treatment (see table 1-2). The next decade will likely see proliferation of the practice of embryo freezing as an adjunct to IVF, although if success in freezing eggs comes about, that would obviate the need for most embryo freezing. Cryopreservation of eggs before fertilization, however, stands as a formidable technical task and may involve an insurmountable biological obstacle—damage to the fragile chromosomes of the oocyte.

Successful pregnancies following micromanipulation of a single sperm into an egg—recorded in neither animals nor humans, to date—would mark dramatic progress in the treatment of male infertility, most of which is caused by too few or abnormal sperm. Ethical and legal concerns regarding proper selection of one human sperm for fertilization may ultimately limit the application of this technology.

Techniques for screening sperm and ovum donors for a limited number of genetic anomalies lie in the foreseeable future. The practical application of genetic screening by practitioners of artificial insemination is uncertain, however, and

Table 1-2.—Some Causes of Increasing Requests for Infertility Services in the 1980s

More couples with primary infertility	Increasing proportion of infertile couples seeking care	Increasing number of physicians providing infertility services	More conducive social milieu	Evolution of new reproductive technologies
• Aging of the baby-boom generation • Delayed childbearing; more people in higher risk age groups • Childbearing condensed into shorter intervals • Delayed conception due to prior use of oral contraceptives	• Decreased supply of infants available for adoption • Heightened expectations • Larger number of people in higher income brackets with infertility problems • Larger percent of infertile couples are primarily infertile	• Greater demand from private patients • More sophisticated diagnosis and treatment • At least 169 sites in the United States offering in vitro fertilization or gamete intrafallopian transfer	• Baby-boom generation expects to control their own fertility • Profamily movement • Increased discussion of sexual matters due to the AIDS epidemic • Extensive media coverage	• Artificial insemination • Surrogate motherhood • In vitro fertilization (IVF) • Gamete intrafallopian transfer (GIFT) • Cryopreservation

SOURCE: Adapted from S.O. Aral and W. Cates, Jr., "The Increasing Concern With Infertility: Why Now?" *Journal of the American Medical Association* 250:2327-2331, 1983.

no amount of screening will exclude all donors capable of transmitting genetic disorders.

Reliable separation of X- and Y-bearing sperm for sex selection remains elusive despite many attempts. When sex selection of human sperm cells becomes possible, its use will be limited by the willingness of couples to undergo artificial insemination or IVF.

The development and use of techniques to select the sex of human embryos are likely to be slowed because techniques developed thus far (for cattle) involve splitting embryos into one part for sexing and another part for transfer. Splitting or biopsying human embryos is certain to be a contentious issue.

One technology of the present, IVF, is itself a powerful means for unraveling mysteries of the human reproductive process. The advent of IVF permits researchers for the first time to view human reproduction in progress. Understanding the interactions between sperm and egg has potentially broad application not only for conception, but for contraception as well. Researchers seeking Federal funding to work in this area, however, have faced since 1980 the stifling effects of a de facto moratorium on Federal funding of research involving human IVF.

POLICY ISSUES AND OPTIONS FOR CONGRESSIONAL ACTION

Nine policy issues related to infertility prevention and treatment were identified during the course of this assessment. They are:

- collecting data on reproductive health;
- preventing infertility;
- information to inform and protect consumers;
- providing access to infertility services;
- reproductive health of veterans;
- transfer of human eggs, sperm, and embryos;
- recordkeeping;
- surrogate motherhood; and
- reproductive research.

Associated with each policy issue are several options for congressional action, ranging in each case from taking no specific steps to making major changes. Some of the options involve direct legislative action. Others involve the executive branch but with congressional oversight or direction.

The order in which the options are presented does not imply their priority. Moreover, the options are not, for the most part, mutually exclusive: Adopting one does not necessarily disqualify others in the same category or within any other category. A careful combination of options might produce the most desirable effects. It is important to keep in mind that changes in one area may have repercussions in others.

ISSUE: Should the Federal Government improve collection of data on reproductive health?

Federal support of collection of data on reproductive health is concentrated in two agencies of the Public Health Service: the National Institutes of Health (NIH) and the Centers for Disease Control (CDC), with its National Center for Health Statistics.

The Federal Government has an interest in collecting data in three areas of infertility: factors contributing to infertility, its prevalence, and the outcome of certain treatments. Few data are consistently collected on factors contributing to infertility at this time. An estimated 20 percent of infertility is a result of sexually transmitted diseases. Gonorrhea, one of the two sexually transmitted diseases known to lead to pelvic inflammatory disease (PID) and thus to infertility, is a reportable disease. But the other, chlamydia, is not. Chlamydial infection is now the most common sexually transmitted disease, and it has significant adverse reproductive consequences, particularly for women.

Nor do much data exist on the prevalence of infertility in the United States. The source most often cited is the National Survey of Family Growth (NSFG), a survey conducted periodically by the National Center for Health Statistics to collect data on fertility, family planning, and related aspects of maternal and child health. Surveys were conducted in 1976 and 1982, and another began in 1988.

There is some concern in the United States that the handling of embryos extracorporeally during IVF might result in increased numbers of birth defects or other health problems in the resulting offspring. NIH has conducted a short-term study of IVF babies born at the Jones Institute of Reproductive Medicine (Norfolk, VA), but no long-term followup is planned. NIH is beginning a study of women undergoing IVF, but this will not focus on the health of the resulting offspring. Thus, there is currently no systematic Federal method for registering the birth of IVF babies and for following the development and health of these individuals.

Option 1: Take no action.

Absent action to make chlamydial infection a reportable disease and thus commence a national surveillance system, researchers and the Government will continue to rely on data obtained from clinics, physician practices, and other health care facilities for estimates of prevalence and incidence of chlamydial infection.

NCHS expanded the questionnaire for the 1988 NSFG, adding more questions concerning infertility. Thus, available information on infertility will improve even without congressional action. The added questions will begin to fill in some of the gaps, such as more information on some factors contributing to infertility, on the prevalence of male infertility, and on infertility treatment.

If Congress chooses not to request monitoring of the health of babies resulting from IVF, the procedure's potentially harmful or beneficial effects on these babies may go undetected. Individual IVF clinics may conduct their own research, but as success rates and the methods of treatment can vary widely between clinics, such research would not be representative of all IVF clinics.

Option 2: Appropriate funds for the Secretary of Health and Human Services to make grants to State public health departments for the establishment of a national surveillance system on chlamydial infection.

A national surveillance system is crucial for control and prevention of chlamydial infection as it would provide quantitative estimates of incidence and prevalence, a basis for identifying infected individuals and those at risk, and a tool for evaluating control efforts. Compared with the piecemeal reporting that now exists, a national system would allow the Centers for Disease Control and the various State health departments to identify high-risk groups and problem areas, thus enabling them to target their funds for screening and education in the appropriate populations and areas. The prevention and treatment of chlamydia that would result from these efforts would likely lead to lower rates of PID and thus to decreased rates of PID-related infertility.

A national surveillance system would require State reporting laws or regulations. Reporting laws not only provide accurate information on the extent and trend of the disease but also promote the involvement of public health authorities in assuring adequate individual patient management and in facilitating screening and education.

Although CDC has consistently recommended that the States establish this surveillance system, individual States are unlikely to do so without additional funds. Congress could appropriate funds for the Secretary of Health and Human Services to make grants to State public health departments, thus helping them handle the costs of making chlamydia a reportable disease.

Option 3: Direct the Secretary of Health and Human Services to enhance the collection of data on infertility.

Congress could direct the Secretary of Health and Human Services, through NCHS, to enhance data collection on infertility. One way this could be accomplished is by increasing the frequency of data collection through a followup telephone survey of the NSFG. Another improvement would be increasing the sample size of the NSFG.

Few data are currently available on male infertility that are based on information drawn from men themselves. NCHS plans to expand the NSFG to include information on the frequency of male infertility, but it will not obtain any information on the factors that lead to it, as the questions will still be addressed to women. To obtain such data on men, a completely different survey addressing men's reproductive health would be necessary. Thus, a third improvement to the collection of data on infertility would be adding a survey of male reproductive health.

Option 4: Establish a systematic method for registering the birth of IVF babies and for following the development and health of these infants.

For the first time in human history, babies are being born following extracorporeal fertilization. Although the incidence of birth defects following IVF does not appear to be disproportionately large, the absence of developmental effects of extracorporeal embryo culture (and perhaps freezing) is not a certainty. Congress could direct the Secretary of Health and Human Services to collect data on the health and development, including psychological development, of IVF babies from birth to maturity to assess the effects of these techniques. The need for such a study could be reevaluated periodically, and the safety and efficacy of other reproductive technologies (e.g., gamete intrafallopian transfer) could also be reviewed periodically. Documentation of good health among individuals conceived by IVF would carry the side benefit of ameliorating some public concern about the procedure.

Pursuit of this option has several costs, particularly as the offspring of assisted conception increase in number. Singling out these individuals for scrutiny raises ethical questions and may be viewed as an intrusion into their privacy. Moreover, the size and cost of such an effort is likely to grow rapidly. Finally, such monitoring forecloses the option of the parents not to reveal to the child the circumstances of his or her conception.

ISSUE: Should efforts toward prevention of infertility be enhanced?

The Federal Government supports no identifiable activities expressly directed toward prevention of infertility. It supports several activities allied with prevention of infertility, such as NCHS collection of descriptive data about infertile couples, contraceptive research funded by NIH and the Agency for International Development, and programs of the Centers for Disease Control that aim to prevent sexually transmitted diseases. Yet the link between these programs and the prevention of infertility has never been prominently forged. As a result, efforts to prevent infertility are not well coordinated within the Federal Government.

Option 1: Take no action.

Under Section 318 of the Public Health Service Act (42 U.S.C. 247c), the Secretary of Health and Human Services, acting through the Centers for Disease Control, is authorized to make grants for the prevention and control of sexually transmitted diseases. Inasmuch as STDs account for an estimated 20 percent of infertility, the Secretary's authority could be used to support programs directed toward prevention of some infertility. Such activities have not been prominent, however, and in the absence of congressional action this situation is likely to continue. In addition, the bulk of infertility is not addressed by programs for prevention of sexually transmitted diseases and is not specifically addressed elsewhere by existing governmental authority.

Option 2: Amend the Public Health Service Act to extend the program of grants for prevention and control of sexually transmitted diseases to include prevention of infertility secondary to sexually transmitted diseases.

Congress could amend the Public Health Service Act to extend specifically the Secretary's authority to make grants for the prevention of infertility believed to be a consequence of sexually transmitted diseases. To be effective, such an extension of authority would need to be accompanied by additional appropriated funds. Amending the Public Health Service Act in this way would focus preventive efforts on the one important preventable cause of infertility identified to date. In addition, such congressional action would have the salutary symbolic effect of raising the apparent priority given to infertility prevention.

A disadvantage of such action is that it might appear to give disproportionate emphasis to STDs as a cause of infertility at the expense of identifying other causes and preventive measures. Pursuit of this option would not address prevention of the majority of cases of infertility, which are not linked to STDs. For those cases, prevention first requires additional research into the factors leading to infertility.

Option 3: Evaluate Federal efforts to prevent infertility.

Congress could direct the Secretary of Health and Human Services to report on Federal activities related to prevention of infertility. Because some efforts in reproductive research fall outside the purview of the Department of Health and Human Services, Congress could direct the Secretary to convene an interagency task force to assess preventive efforts. Or Congress could exercise oversight by means of hearings on this subject. Congressional evaluation of Federal efforts to prevent infertility is likely to identify a need for a coordinated effort that goes beyond prevention of sexually transmitted diseases to consideration of causes of infertility that are not well understood.

Option 4: Establish a demonstration project for identification of risks for infertility.

Beyond sexually transmitted diseases, there are many suspected factors contributing to infertility but few confirmed culprits. Congress could direct the Secretary of Health and Human Services to establish a long-term research effort aimed at identifying exposures or behaviors in young adulthood that predispose an individual to infertility. Such long-term, longitudinal research that follows young adults through their reproductive lives is difficult, expensive, and often exceeds the active research lifespans of individual investigators. In instances like this, therefore, coordinated, cooperative efforts (e.g., the Framingham Heart Study) are required. Such a study is critical for ferreting out confirmed from suspected factors contributing to infertility, and is likely to be a prerequisite to organizing serious programs to prevent whatever portion of infertility can be prevented.

Without a comprehensive longitudinal study to identify risk factors for infertility, many of them may never be fully defined and possible preventive steps may never be taken. On the other hand, the result of such an undertaking may be confirmation that a number of cases of infertility are of unknown origin and not preventable.

Option 5: Enhance education in reproductive health.

Education about reproductive health, as with most education in the United States, is the responsibility of local jurisdictions and largely excluded from the Federal purview. Knowledge of reproductive health is erratic and uneven among individuals of reproductive age; many myths and half-truths are believed as fact. This situation can have important consequences for preventing infertility.

Congress could take at least two steps to enhance education in reproductive health. First, Congress could exercise oversight to see that the Secretary of Health and Human Services, under Title X of the Public Health Service Act, directs health clinics receiving Title X funds to bolster the infertility services offered to their patients. More than 4,000 clinics in the United States serve about 4.3 million people each year. Infertility services constitute about 1 percent of the clinics' activities. This existing network of clinics could make available educational materials and counseling, for example, about the potential long-term infertility consequences of some family planning methods.

Second, Congress could direct the Secretary of Education to develop a model curriculum for primary, secondary, and postsecondary students that illustrates fundamental facts about reproductive health and prevention of infertility. Although it has long been objectionable to some segments of American society, education in reproductive health may be the most cost-effective means at the disposal of the Federal Government for making long-term progress in preventing infertility.

ISSUE: Should the Federal Government ensure that consumers of selected infertility services have the information to make informed choices?

Congress generally does not regulate medical practice, with the exception of drawing broad criteria for care delivered at Veterans' Administration hospitals or reimbursed by Federal insurance programs. Nor are medical techniques subject to consumer protection legislation, with the notable exception of Food and Drug Administration regulations for testing drugs and devices, and for regulating advertising of their indications and efficacy. Rather, quality assurance and consumer protection issues are left to State legislatures, professional societies, consumer groups, and word-of-mouth. However, some have suggested that the Federal Government take steps to ensure that infertile individuals are made aware of the efficacy of the treatments offered and of the success record of medical personnel with whom they are consulting.

This has been particularly stressed with regard to IVF, for several reasons:

- Aspects of the technique are still to some extent in a research phase.
- Success rates vary considerably.
- Success rates are reported in various, and sometimes confusing, ways.
- The procedure is carried out at times in freestanding clinics or other settings that are not subject to all the usual hospital peer-review practices.
- Relevant professional societies do not yet have accreditation programs directed specifically at IVF.
- As the procedure can entail months of drug treatment and repeated surgeries, it can represent a serious health risk and constitutes a major disruption of personal and professional activities.
- IVF is often excluded from insurance coverage, and so may be very costly to individuals.
- The patient population for these services is particularly vulnerable because it largely consists of individuals who have tried for many years to have a much desired pregnancy.

Option 1: Take no action.

Congress could leave quality assurance and consumer protection efforts in the area of infertility services to the individual States and medical professional societies. Other medical services, such as novel techniques for cancer therapy, have similarly suffered from varying success rates and vulnerable patient populations. Absent Federal action, it can be expected that State quality control legislation (such as that enacted in Louisiana), consumer education by private organizations, and medical society activity will attempt to protect patients from the risk, pain, disruption, and cost of undergoing the procedure at clinics or hospitals without a demonstrable success rate. But such efforts will inevitably be spotty for at least the next several years.

By taking no action, Congress would avert bringing public scrutiny to a very private area of health care. It is possible that Federal regulation of infertility services could change the character of those services. Gamete donors, for example, may be unwilling to participate, and recipients of gametes or embryos may be uneasy about medically assisted conception conducted in the spotlight of Federal regulation.

Option 2: Encourage the use of a consensus review or conference on the use of IVF, gamete intrafallopian transfer, and other innovative treatments for infertility.

Short of regulating infertility treatment and research, Congress could facilitate greater data collection and voluntary adherence to guidelines developed by professional societies. This can be done by authorizing the use of governmental agencies or commissioning resources for efforts by professional societies, research institutes, or the insurance industry to hold consensus conferences and to recommend protocols for high-quality care. A consensus conference, for example, could be used to evaluate patient data and to recommend a protocol that lists the best indications for the use of IVF as opposed to gamete intrafallopian transfer. Conferences and reports could also be used to help define a "successful" program; to distinguish experimental techniques, techniques with some possibility of success, and standard techniques; and to make more uniform the minimum level of staffing for a program.

Congress could exercise oversight to encourage NIH or the National Center for Health Services Research and Health Care Technology Assessment to review or hold a consensus conference on innovative infertility treatments. NIH consensus conferences—of which more than 60 have been held in the last decade—could be used to:

- influence the development of data collection on the use of IVF, gamete intrafallopian transfer, and other reproductive techniques;

- recommend indications for use;
- establish conventions for reporting successful outcomes; and
- define standards for laboratory equipment and personnel training.

One important consideration regarding the appropriateness of an NIH consensus conference is whether the questions concerning the medical technology are primarily scientific and clinical, or primarily ethical or economic. The NIH conferences focus on the former. The Office of Health Technology Assessment of the National Center for Health Services Research and Health Care Technology Assessment, under the Office of the Assistant Secretary for Health, has authority to undertake review of less scientific issues, such as safety, efficacy, cost effectiveness, and indications for use of infertility treatments.

Congress could also commission a private research institute or professional society to review current practice of selected infertility treatments and to recommend indications for use, protocols for patient selection, and minimal personnel staffing for clinics. Among the many nongovernmental entities with the resources to perform this function are the American Medical Association, the Blue Cross/Blue Shield Association, and the Institute of Medicine at the National Academy of Sciences.

Option 3: Extend consumer protection laws to selected infertility services.

Congress could direct the Federal Trade Commission to exercise its authority under Section 5(a)(6) of the Federal Trade Commission Act to examine whether advertisement of success rates at various IVF or gamete intrafallopian transfer clinics is misleading, and, if so, to issue appropriate regulations. Regulations could be issued, for example, to standardize the ways in which success rates are reported, so that individuals are better able to make an informed choice about whether and where to undergo a procedure.

Even such consumer regulation is not an effective means of directly regulating the quality of the services offered, however. Regulating a medical service itself—for example, by setting standards for personnel and facilities—would be an unusual step, as such regulation does not generally take place at the Federal level, with the exception of setting quality control standards for Medicare reimbursement.

ISSUE: Are existing mechanisms for gaining access to infertility diagnostic and treatment services adequate?

Currently, those who can afford to pay for infertility services out-of-pocket have the greatest access. To consider use of newer medical technologies, infertile individuals need to be able to pay anywhere from several hundred dollars to more than $22,000. Individuals with some private insurance coverage generally can expect to have a large portion of their expenses covered during the diagnostic phase, with considerable variability of coverage for infertility treatments. Although the majority of health insurance plans have specifically excluded coverage for IVF treatment, there may be a significant amount of reimbursement for the various components of such treatment (e.g., laparoscopy).

Under the Federal Medicaid Program, it is possible to receive reimbursement for infertility diagnosis and treatment if a person is designated as categorically needy and if the State has a policy to submit claims for the reimbursement of infertility diagnosis and treatment services under the heading of "family planning services." States are currently shifting away from the practice of submitting such claims as family planning services.

Under the Federal Medicare Program, it is possible to receive reimbursement for infertility diagnosis and treatment if a person has received Social Security disability benefits for more than 2 years and thus becomes entitled to Medicare coverage. It is not clear how many disabled individuals of reproductive age have actually sought or received this coverage.

There are geographical as well as financial determinants of access to infertility diagnosis and treatment. For the initial medical consultation regarding this problem, couples are most likely to seek the advice of their gynecologist, general practitioner, or urologist. If the problem is serious enough for referral to an infertility specialist, access to such care is likely to be reduced. Sophisticated infertility care is generally located in urban areas. Innovative, experimental procedures for more difficult infertility cases are more likely to be available at universities and medical centers.

Option 1: Take no action.

If Congress takes no action, then access to physicians and diagnostic and medical care for infertility will continue to be determined by individual financial resources and geography. This may lead to an inequitable distribution of infertility services among socioeconomic classes or geographical areas. On the other hand, by taking no action Congress will avoid imposing upon some citizens a responsibility to support certain medical procedures they may consider purely elective or immoral.

Option 2: Direct the Health Care Financing Administration of the Department of Health and Human Services to review and report on the extent of existing coverage for infertility diagnosis and treatment services under the Medicaid and Medicare Programs.

Current reporting schemes under Medicare and Medicaid do not identify which diagnostic and therapeutic infertility procedures are covered and how much they cost. This information would provide an important basis for decisions about any changes needed in the Medicaid and Medicare Programs.

Option 3: Amend the existing Federal Medicaid Program to add a new reimbursement category for services related to the diagnosis and treatment of infertility.

Amending Medicaid coverage would establish consistent national policy for infertility diagnosis and treatment coverage. It would no longer be at the discretion of the States to decide whether or not to submit claims for reimbursement of infertility services under the heading of "family planning services." This change in Medicaid reimbursement policy would likely result in increased demand for reimbursements for infertility services. It could also be viewed as equivalent to a finding of ethical acceptability or unacceptability by the Federal Government with regard to each procedure allowed.

Option 4: Amend Title 5 of the U.S. Code to provide that any carrier offering obstetrical benefits under the health benefits program for Federal employees shall also provide benefits for medical procedures to overcome infertility, including procedures to achieve pregnancy and to carry pregnancy to term.

Insurance programs for Federal workers could be required to cover all diagnosis and treatment of infertility. The existing Federal Employees Health Benefits Program covers the costs of pregnancy and delivery and some forms of infertility diagnosis and treatment. Less traditional techniques, such as IVF, gamete intrafallopian transfer, and artificial insemination, arguably merit similar coverage. Although such legislation would benefit only the Federal work force, it could serve as a model to private insurers and employers. Such a model would provide a database of cost information upon which private plans could be constructed.

Implementation of this option could cause some insurance carriers to drop obstetrical benefits en-

Photo credit: Library of Congress

tirely. Those carriers who expand their coverage would likely increase the premiums charged Federal employees and the Government.

Option 5: Facilitate adoption, a social alternative to infertility treatment.

Some couples seek medical or surgical treatment, or a surrogate mother, because adoption is for them too difficult or time-consuming. Adopting through a public agency can entail a wait of 2 to 10 years and stringent eligibility criteria; private, independent adoption can be expensive and take from 6 months to 5 years. Congress could work to facilitate adoption by examining the results achieved under the Adoption Assistance and Child Welfare Act of 1980, the Title IV funding of child welfare (including foster care) and adoption assistance under that act, and the 1978 Child Abuse Prevention and Treatment and Adoption Reform Act. These programs could be used to develop a national database of adoptable children for use by couples seeking private adoption, as well as to remove barriers to the adoption of children with physical or mental handicaps, older children, or children of a different race.

Many available children in this country are never adopted because individuals find the prospect of an interracial family, a difficult adjustment period for an older child, or a lifetime of care for a handicapped child to be too daunting. Further incentives and social services could be used to help ease these difficulties, and better use of a national clearinghouse for all adoptable children may make the process of adoption, even if lengthy, more manageable and successful. Even with more services, however, such adoptions are not likely to be attractive to all individuals seeking to form a family. For some, the purpose in seeking infertility treatment or a surrogate mother is to have a child who is genetically related to at least one parent. Adoption cannot satisfy this desire.

ISSUE: Should the Veterans' Administration provide infertility diagnosis and treatment?

For the VA to provide care to a veteran, at least four conditions must be met: the veteran must have a disability, the VA care must be for that disability, the care must be necessary, and the care must constitute hospital care (including medical treatments). These provisions mean that veterans currently obtain only limited treatment for infertility from the VA.

During the 100th Congress, on Dec. 4, 1987, the Senate passed an amendment to Section 601(6) of Title 38 of the U.S. Code. This would give the VA authority to provide "services to achieve pregnancy in a veteran or a veteran's spouse where such services are necessary to overcome a service-connected disability impairing the veteran's procreative ability." A similar provision had been passed by the Senate (but not the House of Representatives) during the 99th Congress.

Option 1: Take no action.

The present position of the VA prevents it from treating infertility since the agency does not interpret infertility to be a disability (defined as a disease, injury, or other physical or mental defect). Although some infertility medical workup may be performed, procedures such as IVF, gamete intrafallopian transfer, and artificial insemination may not be provided. In addition, the VA lacks authority to treat a nonveteran spouse for infertility.

Financial arguments for taking no action are supported by the fact of the aging of the veteran population—increased expenditures by the VA for costly and elective medical procedures may not be justified. If additional funds are to be allocated to the VA for health care, these funds might best be used to improve and expand treatment of life-threatening disorders. Further, taking no action means the VA need not make judgments about fitness for parenting.

On the other hand, the comparatively small number of veterans with service-connected infertility means the VA would not incur substantial expenses in contracting for infertility services. In addition, the VA's mission is to provide health care to eligible veterans. This health care is not limited to life-threatening disorders, as evidenced by the wide range of services the VA already provides.

Option 2: Direct the Administrator of the Veterans' Administration to interpret disability to include the inability to procreate.

If Congress proceeds with this action, the Veterans' Administration could offer infertility treatment under existing statues and regulations without other specific legislation. Treatment of the nonveteran spouse, however, would remain beyond the authority of the VA. Therefore, treatment of infertility under this option would probably be restricted to specific cases of infertility where the disorder was found solely in the veteran partner. This option would still permit the VA to proscribe particular infertility treatments as being experimental or too expensive, and to limit its coverage to traditional medical or surgical therapy.

In a variation of this option, Congress could elect to mandate that infertility be considered by the VA a secondary disability or an inevitable consequence of disease and therefore compensable. Infertile veterans could then obtain some funds to be treated privately.

Option 3: Amend Title 38 of the U.S. Code to specify that infertility treatments including but not limited to IVF, gamete intrafallopian transfer, and artificial insemination may be provided by the Veterans' Administration.

These treatments could be made available only to veterans with service-connected infertility but not their spouses, only to veterans with service-connected infertility and their spouses, to all infertile veterans but not their spouses, or to all infertile veterans and their spouses. Forms of infertility treatment that do not require hospital care especially require authorization through legislation, as VA regulations preclude such outpatient treatment. The disadvantage of this course of action is that any listing of infertility services may be viewed as exclusive and may not encompass emerging technologies.

The VA could administer such treatment in several ways. Infertility treatment units could be set up in all VA medical centers and offer services such as hormonal workup, semen analysis, fertility drugs, IVF, gamete intrafallopian transfer, artificial insemination, and other reproductive technologies. Since many of these services and treatments are not presently offered by VA medical centers, this option would involve a major commitment of funds to hire new staff such as gynecologists, reproductive endocrinologists, andrologists, reproductive tract microsurgeons (where surgical facilities are available), and laboratory personnel. The VA's relationship with medical schools would be affected in that new affiliations would be needed, for example, with departments of obstretrics and gynecology.

A limited number of regional or district infertility treatment centers could be set up in various VA Medical Centers, depending on the need. As with the preceding approach, this would involve hiring new staff and setting up infertility diagnostic and treatment laboratories. This would probably be most successful if regional infertility centers were established in VA hospitals closely associated with academic or medical institutions with programs for infertility treatment.

The VA could contract with other health care providers that have infertility treatment programs for the treatment of eligible veterans with infertility problems. Contract health care already exists within the VA for medical treatments such as gynecological services not generally available in a VA center. In addition, contract health care may be provided if VA facilities are not within a reasonable geographical distance. However, under the provisions for contract health care (38 U.S.C. 608), the eligibility for treatment is more limited than in VA facilities.

The VA could provide infertility treatment in some cases as part of the Civilian Health and Medical Program of the VA (CHAMPVA). This program provides health care for survivors and dependents of certain veterans. The criteria for eligibility are that the veteran must have a total disability, permanent in nature, resulting from a service-connected disability. The disability rating must be 100 percent. This approach would most likely provide benefits to a very limited population, although it may benefit veterans with spinal cord injuries since these individuals are classified as having total or near-total disabilities.

It is important to note that CHAMPVA provides the same health care benefits as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). These benefits include coverage of most types of infertility diagnostic and treatment procedures. Under CHAMPUS, however, artificial insemination, IVF, and gamete intrafallopian transfer are specifically excluded, as are any treatments that involve artificial conception. Although this approach may allow for the medical treatment of nonveteran spouses, other changes in CHAMPVA eligibility and benefits may be needed.

Lastly, Congress and the VA could provide infertility treatment for veterans by making available a one-time voucher or grant to infertile couples for the cost of procedures such as artificial insemination, IVF, and gamete intrafallopian transfer. These treatments would then be obtained from health care providers other than the VA. In most cases, grant-type benefits operate on an actual expense basis, with the VA either paying the bill directly or reimbursing up to a maximum amount. Questions that arise with this approach include the amount of the grant, and the responsibility of the VA to the couple and the offspring.

ISSUE: Should the transfer of human gametes and embryos be regulated?

Sperm are sold by commercial sperm banks throughout the United States and have been for many years. The Food and Drug Administration has authority, within its Center for Devices and Radiological Health, to regulate tissues, including semen. In 1988, FDA and professional societies involved in artificial insemination laid out new standards regarding storage and use of semen to protect semen recipients from infection with human immunodeficiency virus.

Donation of unfertilized ova is today occurring at a number of infertility clinics. A few have begun to pay women to undergo hormone stimulation and ovum retrieval, sometimes in the course of voluntary sterilization by tubal ligation. Ovum banking using frozen ova has yet to become available, but considerable research is under way to make this feasible.

Embryos that remain after IVF procedures are not yet sold, as clinics and hospitals have chosen instead to give parents the choice of having them frozen, destroyed, or donated. No technological obstacle exists to maintaining commercial embryo banks, although there is still a significant rate of embryo loss associated with freezing.

Option 1: Take no action.

Taking no action regarding the transfer of human gametes and embryos would be in keeping with the strong tradition of nonintrusion of the Federal Government into reproduction. If Congress takes no action, the majority of sperm banks will probably continue to pay donors for their semen and to charge recipients for the sperm. Screening of donors for genetic and infectious diseases will continue to vary among sperm banks, influenced by the periodic promulgation of standards by various professional medical societies, and inconsistently regulated by State laws.

Commercial embryo banking may develop, and guidelines for selecting recipients and setting prices could follow the model of sperm banking. State laws may be passed affecting the circumstances of the sales, such as provisions concerning recordkeeping, anonymity, or pricing, while other States may pass legislation banning the sales altogether. It is not certain whether such bans would withstand constitutional challenges based on State interference with the right to procreate.

Option 2: Mandate national standards for protection of paid ovum donors.

Although sperm donation entails no appreciable physical risk to the donor, ovum donation requires either abdominal surgery or sonographic-guided oocyte retrieval, both of which entail some added risk of infection and other complications to the donor. Women who donate extra eggs in the course of their own infertility treatment face no added risk.

Congress could enact legislation or direct the Secretary of Health and Human Services to issue regulations to protect ovum donors by requiring, for example, that commercial sales of ova (or embryos) be allowed only with ova obtained during a therapeutic or diagnostic procedure. This would effectively bar the development of a pool of women who are paid to undergo a medical procedure of some risk, when that procedure has no ancillary benefit to themselves.

Some may object that such a bar would be discriminatory, as men could continue to earn money by selling their sperm. Further, barring adult women from doing this may be seen as inconsistent with the fact that they can choose to be paid for other, more physically dangerous tasks.

Option 3: Mandate national standards for protection of recipients and offspring.

Congress could enact legislation directing the Secretary of Health and Human Services to set minimum standards for screening egg and sperm donors for serious genetic disorders and infectious diseases that could be passed on to recipients of their gametes or the resulting children. National standards could be based on adoption of existing professional society guidelines, with periodic reexamination of the efficacy of tests for human genetic disorders. Even if such standards were directed only at commercial gamete and embryo banks, they would provide significant guidance as to the minimum standard of care that ought to be met by unregulated providers, such as individual physicians.

Some may assert that national standards are likely to take longer to develop and to revise than those produced periodically by professional medical societies. Further, development of effective standards would probably require some kind of reporting and enforcement mechanism, unless the standards are to be used only to create a presumptive standard of care for use in individual cases of medical malpractice litigation.

Congress could also facilitate the development of a national databank on gamete donors (as South Africa has done), so that the number of donations from any one person could be limited. This could avoid the problem created when a single donor is used to initiate a large number of pregnancies, introducing some risk of unintended consanguinity among future marriage partners. This is of concern mainly in areas in which there are few donors supplying sperm for a geographically isolated population.

Further, the databank could be used to allow gamete banks to share information on the genetic and physical health of donors. Combined with followup reporting on the offspring, such recordkeeping practices could also facilitate identification of donors shown to suffer from previously undetected genetic disorders, making it possible to prevent those persons from again selling gametes.

Reports in several other countries have recommended that the number of donations per donor be limited. In France, sperm banks keep strict records and limit the number of donations per person. The central organization of the sperm banks in France, however, is quite different from the large number of independent banks in the United States. The Warnock Committee in the United Kingdom proposed the most comprehensive plan, recommending that there be a central registry of donors that must be checked every time a clinic accepts a donor. South Africa does this by law. Any registry of donors carries the risk that it will decrease the willingness to donate of those individuals who prefer anonymity.

Option 4: Ban commercial sales of embryos.

Congress could amend the National Organ Transplant Act to outlaw the buying or selling of embryos. Some view the sale of embryos as making the human body a commodity and therefore unacceptable. Others view the sale of embryos as the unacceptable commercialization of a genetic blueprint. Embryos are generally viewed as deserving especially respectful treatment, and sales of embryos offends many persons who find it too close to the sale of babies or who fear that embryo sales may lead to classification of some embryos as more desirable than others. Further, permitting the sale of embryos could in some cases lead donors to undertake medical risks for pay.

On the other hand, such a ban could be viewed as an intrusion that limits the freedom of donors to engage in commerce. Further, a ban on commercial sales of embryos may be subject to constitutional attack as State interference with the right to procreate.

A ban on commercial sales of embryos will not necessarily greatly reduce the supply of gametes. Some countries, such as France, do ban such sales, and yet have managed to maintain successful sperm donation programs. Nevertheless, the U.S. market economy and culture may make such comparisons inappropriate.

ISSUE: Should anyone accepting or transferring human gametes keep nonidentifying genetic records on behalf of the potential child?

Donation of human gametes is usually accompanied by an oral patient history including important genetic information that can become a formal written record. Such information is routinely obtained by those who operate sperm banks as they screen donors. Currently, however, the type of information that is collected and the ways in which it is maintained and transferred vary greatly. This variation is particularly significant because the predictive value of genetic history may increase in coming years.

Option 1: Take no action.

If Congress takes no action, the transfer of such information will continue to occur in an occasional manner, and children born as a result of reproductive technologies that make use of donor gametes (i.e., IVF, gamete intrafallopian transfer, artificial insemination by donor, and surrogacy) will not have access to genetic information that might be vital to their health.

On the other hand, the medical community has not achieved consensus on the utility of minimal information about individuals' genetic heritages. The ethical and financial costs of collecting genetic information about gamete donors must be weighed against its ultimate usefulness.

Absent any congressional action, individuals who obtain or transfer human gametes (or embryos) may or may not adhere to the recommendations of professional associations such as the American College of Obstetricians and Gynecologists and the American Fertility Society to maintain a permanent record of minimal genetic screening information. The AFS's 1986 recommendations for a minimal genetic screen of gamete donors specify that practitioners maintain a permanent record that preserves confidentiality. The record should include the genetic workup and other nonidentifying information and should be made available on request—on an anonymous basis—to the recipient or resulting offspring.

Concerns about establishing a child's genetic endowment should be viewed in an important context: Some children born of married couples who did not use medically assisted conception were not sired by the father of record.

Option 2: Mandate that operators of sperm, ova, and embryo repositories, or anyone who transfers these materials, maintain written records detailing the nonidentifying genetic history of all gamete donors and that this information be available to the recipients of gametes or embryos and the eventual offspring.

If Congress were to enact such a law, or simply encourage standardization of recordkeeping on a voluntary basis, it would result in retention of information that currently may be lost or deliberately discarded in the interest of protecting the anonymity of gamete donors. It would reduce the extent to which some members of future generations may suffer from genealogical bewilderment resulting from the inaccessibility or loss of important information about their genetic endowments.

Such a law would somewhat increase the recordkeeping of those who are currently involved in the storage and transfer of human gametes and embryos, although much of this information is already being collected. Although much pertinent genetic information is already obtained in the process of screening potential gamete donors, the enactment of a new law would result in an increased recordkeeping burden for all such individuals. The occasional practice of mixing sperm from more than one source would also increase the complexity of such recordkeeping.

More complicated variations of this course of action include maintenance of white blood cells from gamete donors as a complete and retrievable genetic record, and recordkeeping with information that identifies the gamete donors. Both raise serious concerns about logistics and privacy.

ISSUE: Should commercialized surrogate motherhood be regulated by the Federal Government?

Surrogate motherhood is an infrequent but increasingly popular arrangement used by infertile couples, singles, and homosexuals as an alternative to adoption and perhaps infertility treatment in their efforts to form a family. Surrogacy arrangements are based upon principles of contract and family law, and therefore are largely within the traditional domain of State legislative activity.

With surrogacy an interstate business, Congress has the power under the Interstate Commerce Clause of the U.S. Constitution to enact regulatory legislation, but, just as with respect to interstate adoption activity, Congress may choose to leave this area primarily to State and local oversight. Coordination of State legislative efforts has not taken place, with the exception of activities of committees of the National Conference of Commissioners on Uniform State Laws and of the American Bar Association.

Option 1: Take no action.

Absent Federal direction, surrogate motherhood is likely to be subject to extensive State legislative debate and action over the next few years. State legislation, when enacted, is likely to vary considerably, ranging from complete bans to only minimal oversight of contractual arrangements. This period of State legislative activity may be a useful experiment for finding a workable legislative scheme to either ban or promote the practice. Or lengthy and complicated custody battles could ensue if courts must first decide which State's law applies to the case (so-called choice-of-law questions). The problem can become particularly acute if the choice of using one State's law rather than another's could essentially decide the case. Lengthy custody suits are troubling because it becomes progressively more difficult to remove the child from his or her initial home, regardless of the merits of the case. Numerous custody battles may exact a heavy toll on the families and children involved.

Option 2: Review developments in State law related to surrogate motherhood.

Congress could exercise oversight to examine the trends in State law regarding surrogate motherhood to ascertain whether Federal action is necessary. Topics of interest could include State legislation and case law on resolution of custody disputes; development of standard contract provisions, including provisions relating to a surrogate's choice of diet, medical care, and pregnancy continuance; fee structures; and protection for offspring in the event of death or disability of an adult participant.

Option 3: Facilitate development of State legislation related to surrogate motherhood.

Congress could authorize the use of challenge grants to encourage States to explore approaches to surrogate motherhood. Funds could be used to finance studies of proposed legislation; to begin pilot projects for licensing of professional surrogate matching services or review of surrogate contracts; to determine the need for home studies of couples seeking a surrogate mother; or to carry out research concerning the psychological impact of surrogacy arrangements on a child, any siblings, and the adult participants.

Option 4: Facilitate interstate cooperation and harmonization of State laws.

Congress could facilitate joint efforts by States to develop a uniform approach to surrogate motherhood. Congress could pass a joint resolution, for example, calling on States to adopt one of the model laws now being developed by various professional groups, such as the American Bar Association or the National Conference of Commissioners on Uniform State Laws. Congress could also draft such a model law itself, to be published in the Federal Register, as was done in a 1981 effort to harmonize State adoption laws with respect to children with special needs.

Although neither a joint resolution nor model legislation is binding upon the States, either could be used to express the sense of Congress concerning the use of surrogate motherhood. Congress could also encourage States to develop interstate compacts in order to avoid difficult choice-of-law problems in the event of a custody dispute surrounding an interstate arrangement, and to harmonize regulations concerning surrogate mother matching and child placement. The Interstate Compact on Placement of Children provides a precedent for the use of such compacts in the area of family law, in that case with respect to placing children in foster care or adopting homes.

Option 5: Mandate national standards for surrogate motherhood arrangements or commercial intermediaries.

Congress could enact legislation directing the Department of Health and Human Services to set national standards for the practice of matching surrogate mothers to individuals seeking to hire them, or for the arrangements themselves. Such standards could include medical or psychological screening for surrogates and prospective rearing parents; recordkeeping requirements to allow children access to medical or personal data on their genetic and gestational parents; limitations on advertising techniques, referrals, and fees; and licensing requirements for the commercial intermediaries. These standards could also include limitations on the substantive provisions of the contracts professionals might offer to the participants. Limitations might include provisions concerning the restrictions placed upon the surrogate's lifestyle, choice of medical care, or right to terminate her pregnancy, and those concerning presumptions of custody.

Some argue that, as with regard to adoption, such regulation is best left to individual State legislatures. Others assert that as an interstate business, and potentially international business, surrogate mother matching is an appropriate subject of Federal attention.

In lieu of Federal licensing legislation or regulations, Congress could exercise its spending power to attach conditions to the receipt of Federal funds to require States to license professional surrogate matching services. For example, conditions could be attached to Federal funding for Aid to Families with Dependent Children, family planning agencies, or adoption assistance programs. Some of these programs are heavily dependent on Federal funding, and many States would probably feel compelled to pass the necessary legislation.

Absent Federal action, a patchwork of State legislative limitations and State court decisions is likely to influence the substantive content of surrogacy contracts and the persons able to use them.

Option 6: Facilitate international agreements concerning transnational surrogacy arrangements.

Already in the brief history of commercialized surrogate motherhood, women from other countries have contracted with American women to act as surrogates, and vice versa. This may become more common in the future. Gestational surrogacy (i.e., where a woman carries a child to whom she is genetically unrelated) may also become more common. Affluent couples, for example, could hire women from developing nations, for whom a fee of far less than $10,000 would still constitute a considerable sum.

To ensure that there is no confusion concerning the rights of these women, and to avoid conflicts of national law concerning maternity and child custody in the event of a dispute, Congress could work to facilitate international cooperation and agreement on transnational surrogacy arrangements. This could be accomplished by submitting proposals to amend one of the existing child welfare agreements (e.g., the Hague Convention on International Parental Kidnapping), in order to state clearly who, at least initially, shall be considered the mother and the father of a child, and who shall have initial rights to physical custody.

Option 7: Ban commercialized surrogate motherhood.

Congress could enact legislation to ban for-profit surrogate motherhood, leaving individuals able to engage in the practice as long as no money beyond actual expenses changed hands. Such a ban would probably have the effect of drastically reducing the scope of the practice. It would, however, be subject to constitutional challenge by those who assert that paying a surrogate mother is a protected aspect of reproductive liberty.

Alternatively, Congress could outlaw commercial intermediaries while leaving individuals free to make their own arrangements even if they involve payments to the surrogate. This too would probably reduce the scope of the practice. And while the same constitutional challenge could be mounted, it would be somewhat more difficult to maintain.

Bans on payments to surrogates or intermediaries or both could be designed as either civil offenses (for which one pays a penalty) or criminal offenses (for which one can be fined or jailed). Criminal penalties, particularly if directed toward the individual surrogates and couples, are likely to engender the most serious judicial challenges.

It is possible that any attempt to ban surrogate motherhood may drive the practice—which in some cases can be done without doctor or lawyer—underground. This may reduce the frequency of the practice, but increase the medical and legal risks to the participants.

ISSUE: Do some areas of reproductive research require additional support?

Federal support of human reproductive research is concentrated in two agencies of the Public Health Service: NIH (in particular, the National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences) and CDC (in particular, the National Institute for Occupational Safety and Health and the National Center for Health Statistics). In addition, the National Science Foundation, the Environmental Protection Agency, the U.S. Department of Agriculture, the Department of Defense, the Department of Energy, the Agency for International Development, and the VA fund reproductive research involving humans or animals.

Option 1: Take no action.

In the absence of any targeted congressional action, research in broad areas of human and animal reproduction will continue to be supported by the Federal agencies listed. Research in male reproductive biology has historically lagged and will likely continue to do so in the absence of a special compensatory effort.

Research that involves fertilization of human sperm and eggs is today in effect excluded from Federal support because of the absence of an Ethics Advisory Board (EAB) within the Department of Health and Human Services; such a board is required to advise the Secretary as to the ethical acceptability of such research (45 CFR 46.204(d)). Without congressional oversight, the failure since 1980 of successive Secretaries of Health and Human Services to appoint an EAB is likely to continue. Consequently, questions surrounding the interaction of sperm and egg—fundamental to an understanding of conception and contraception—remain largely uninvestigated.

In addition, research into the efficacy and risks of some infertility treatments such as IVF and gamete intrafallopian transfer are largely uninvestigated and lie outside the sphere of Federal funding and peer review. Finally, in an era of heightened concern about the ability of the United States to compete internationally, it is noteworthy that major developments in early embryo research are most likely to occur in nations such as Australia and the United Kingdom, where the research climate is more favorable.

Option 2: Expand Federal support for research in male infertility.

With the principal cause of male infertility being abnormal or too few sperm, due to unknown factors, efforts on prevention and treatment are largely guesswork. Some contend that studies of the reproductive health of men have been poorly designed and are too inadequate to draw any firm conclusions.

Congress could direct the Secretary of Health and Human Services to convene an interagency task force to report on the scope and adequacy of Federal research efforts into the reproductive health of men. Congress could direct the task force to identify a coordinator and an appropriate lead agency for a strengthened, government-wide effort to identify the causes of and treatments for male infertility.

Such an effort would probably require a 5- to 10-year sustained commitment of additional funds for research. The outcome of such a commitment would likely be positive identification of some risk factors for male infertility that are today unrecognized. In addition, long-sought-after progress in development of male contraceptive methods is likely to accompany advances in understanding male infertility.

It is important to note that expanded Federal support for research in male infertility does not represent an alternative to continued research in female infertility. Both are required for progress in understanding infertility.

Option 3: Expand Federal support for research on the psychology of participants in assisted conception.

The positive and negative impacts of infertility and novel reproductive technologies on the behavior of individuals and on society as a whole have been little studied. Congress could exercise oversight to see that the research agencies that support the social, behavioral, and psychological sciences place research on the psychology of participants in assisted reproduction high on their priority lists.

Photo credit: David M. Phillips

Rabbit sperm fertilizing rabbit egg

Option 4: Direct the Secretary of Health and Human Services to review, solely for scientific merit, research involving human sperm, eggs, and early embryos.

In some other nations, Governments and advisory bodies have declared that it is acceptable to do research with human sperm and eggs and with embryos of not more than 14 days of age. Congress could direct the Secretary of Health and Human Services to consider in routine fashion proposals to conduct such research (i.e., review them solely for scientific merit) and specifically exempt them from the regulatory requirement for review by an EAB.

Option 5: Mandate the appointment of an Ethics Advisory Board within the Department of Health and Human Services.

In 1974, the Department of Health, Education, and Welfare established an EAB to review research proposals that raise sensitive ethical questions. Since 1980, no Board has been appointed. Areas of infertility research that raise sensitive ethical questions, such as research into the events surrounding human fertilization, are directly affected by the absence of an EAB. Such research cannot be funded by the National Institutes of Health without review by an Ethics Advisory Board. Congressional oversight may be sufficient—or legislation may be required—to resolve the question of the failure of the Department of Health and Human Services to abide by its own regulation requiring appointment of an EAB.

Option 6: Direct the Secretary of Health and Human Services to implement (and update as needed) the 1979 recommendations of the Ethics Advisory Board.

The 1979 report of the EAB of the Department of Health, Education, and Welfare found that research involving human IVF is ethically acceptable. It concluded that "a broad prohibition of research involving human IVF is neither justified nor wise."

With regard to Federal support of research involving human IVF, the Board concluded that Federal involvement is ethically acceptable and might help to resolve questions of risk and avoid abuse by encouraging well-designed research by qualified scientists. Further, Federal involvement might help shape the use of the procedures through regulation and by example. The conditions, for example, under which researchers could manipulate embryos that are not transferred following IVF would almost certainly be defined in any federally supported research protocol.

Congress could mandate that the Secretary of Health and Human Services incorporate the 1979 conclusions and recommendations of the EAB into departmental practice, updating them as needed. This action, along with appointment of an EAB, would likely end the de facto moratorium on Federal support for research involving human IVF. Increased research into the efficacy and risks of IVF and allied procedures would provide a base of knowledge to protect infertile couples who are today readily availing themselves of such procedures.

Option 7: Direct the congressional Biomedical Ethics Board to develop guidelines for federally funded research with human sperm, eggs, and embryos.

Unlike the United Kingdom, Australia, and a number of other nations, the U.S. Government has not formally evaluated the prevailing ethical standards surrounding reproductive technologies. The congressional Biomedical Ethics Board was established to report on the ethical issues arising from the delivery of health care and biomedical research, including the protection of human subjects of such research.

Congress could direct this Board to report on the ethical implications of public policies related to artificial insemination, egg donation, cryopreservation of gametes and embryos, IVF, surrogate motherhood, and other biological and social solutions to infertility. Such a report would establish ethical guideposts for Federal agencies supporting research in these areas. In addition, it would serve the valuable historical purpose of standing as a landmark of the limits on ethically acceptable research and clinical care as American society enters the 1990s.

Chip Moore
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Chapter 2

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Chapter 2

Introduction

About 3.8 million babies were born in the United States in 1987. This report is about the portion of those babies conceived with medical assistance —babies who were desired but who could not be routinely conceived or carried to term without help. Most of all, this report is about the adult men and women who undergo months and years of invasive medical diagnosis and intervention in order to have a baby.

Infertility has always been a concern for those affected, but beginning with baby Louise Brown, the first person conceived outside of a human body, and continuing through the surrogate mother case of Baby M, the public's collective imagination has been captured by new options in the age-old process of procreation. At the same time, new and provocative scientific, legal, economic, and ethical questions about conception have arisen. Therefore, at the request of the Senate Committee on Veterans' Affairs and of the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Operations, OTA undertook this broad study of the factors leading to infertility and of its prevention and treatment.

This report covers the scientific, legal, economic, and ethical issues surrounding medically assisted conception, surgically assisted conception (including in vitro fertilization and gamete intrafallopian transfer), artificial insemination, basic research supporting reproductive technologies, and surrogate motherhood. The recent attention to these techniques should not obscure the fact that many have been in existence for some time (see table 2-1).

This report is limited to technologies that help establish a pregnancy. Certain allied issues, such as management of pregnancy, prenatal diagnosis including embryo biopsy, termination of pregnancy, fetal research, child health, adoption, and alternate family arrangements involving child sharing are beyond the scope of this report. OTA has recently reported elsewhere on technologies for child health (9).

DEFINING INFERTILITY

The standard medical definition of infertility is the inability of a couple to conceive after 12 months of intercourse without contraception. There are several variations on this definition, such as:

- the inability of a woman to conceive after 12 months of intercourse without contraception (1);
- the inability to conceive a pregnancy after a year or more of regular sexual relations without contraception or the incapacity to carry a pregnancy to a live birth (6);
- the inability of a woman to achieve a first pregnancy after engaging in sexual activity without using contraceptive methods for a period of 2 years or longer (4);
- the inability of a couple to conceive after 2 years of intercourse without contraception (2); and
- the inability of male and female gametes (sperm and ova) to fertilize and appropriately implant (3).

An ongoing study of the epidemiology of infertility conducted by the Centers for Disease Control reveals that the standard medical definition of infertility is a poor predictor of future conception: Only 16 to 21 percent of couples meeting this definition actually remain infertile throughout their lives (2). With an increase since 1980 in visits to physicians for infertility treatment (see ch. 3), the choice of a definition has important clinical implications. Under a more stringent definition, the predictive value is more accurate and interventions can be initiated with some precision. If a broader definition is used, predictive value decreases but interventions may be sought earlier by a greater proportion of individuals who may eventually need them. This OTA report adopts the standard medical definition of infertility be-

Table 2-1.—Some Landmarks in Reproductive Technology

	In animals	In humans
1782	Use of artificial insemination in dogs	
1799		Pregnancy reported from artificial insemination
1890s	Birth from embryo transplantation in rabbits	Artificial insemination by donor
1949	Use of cryoprotectant to successfully freeze and thaw animal sperm	
1951	First calf born after embryo transplantation	
1952	Live calf born after insemination with frozen sperm	
1953		First reported pregnancy after insemination with frozen sperm
1959	Live rabbit offspring produced from in vitro fertilization (IVF)	
1972	Live offspring from frozen mouse embryos	
1976		First commercial surrogate motherhood arrangement reported in United States
1978	Transplantation of ovaries from one female to another in cattle	Baby born after IVF in United Kingdom
1980		Baby born after IVF in Australia
1981	Calf born after IVF	Baby born after IVF in United States
1982	Sexing of embryos in rabbits Cattle embryos split to produce genetically identical twins	
1983		Embryo transfer after uterine lavage
1984		Baby born in Australia from embryo that was frozen and thawed
1985		Baby born after gamete intrafallopian transfer (GIFT) First gestational surrogacy arrangement reported in the United States
1986		Baby born in the United States from embryo that was frozen and thawed

SOURCE: Office of Technology Assessment, 1988.

cause it is most consistent with the accumulating database regarding the behaviors of individuals seeking infertility treatment (see ch. 3).

Factors that contribute to infertility may be attributable to a man, a woman, or a couple as an entity, or they may be unknown. Likewise, treatment may be directed toward a man, a woman, or both together. In some instances, infertility may resolve without treatment. Couples who have been unable to conceive for months or years may suddenly do so with no medical assistance. In contrast, other couples may have conceived children in the past but find themselves unable to conceive again. In the broadest sense, infertile couples include not only those who are childless but also those with fewer children than they desire. (See box 2-A for a discussion of the impact of infertility on a couple.) The important reasons for treating infertility as a shared condition do not obviate concern for infertility as occasionally an individual problem. A young man, for example, who discovers he has a low sperm count may want that investigated and, if possible, treated, even if he is not at that time thinking of forming a family.

IS INFERTILITY A DISEASE?

Infertility has been characterized as a disease, disorder, disability, handicap, illness, syndrome, condition, or condition caused by disease. These terms are used to describe, explain, and evaluate clinical problems. The simple assertion that infertility is a disease has both advantages and disadvantages. For one thing, achieving a pregnancy may not *cure* the underlying cause of infertility.

Box 2-A.—Impact of Infertility on a Couple

Infertility is a painful private experience. The fertile world is unprepared to provide a comfortable opening for the individual or couple who is experiencing the pain of wanting a child and not being able to achieve a pregnancy and birth. Sadness, depression, and avoidance of baby showers, maternity shops, children's toys, and pregnant friends can often be misunderstood.

The couple finds that the infertility experience invades many areas of their lives. Work, at times the only escape from other distresses, can become a place of deception and some risk. The business trip conflicts with scheduled intercourse. Frequent late arrivals due to doctor's visits and irritability from stress or drug side effects are disguised as some other illness or problem.

Partners often cannot even count on each other for the needed support and understanding. The acceptance of infertility and the road to its resolution are individual experiences. No two persons, married or not, proceed through this process at the same pace. Learning to accept their infertility may put a terrible strain on partners' love for each other. Sometimes partners disagree on the medical efforts they are willing to pursue in order to conceive a child. One person may wish to continue treatments, while the other may be ready to stop. Or, one may be willing to explore adoption while the other still wishes to pursue options for having a genetically related baby. Even when both agree to pursue adoption, there may be disagreements such as whether to seek a baby of another ethnic group or perhaps with a disability. All these strains may cause a reassessment of their commitment to have a baby or continue their marriage.

Some fertile partners are reluctant to discuss their own sadness for fear of making their mate feel guilty or responsible. Others make their anger clear. Some infertile people provocatively suggest that the fertile partner could have a baby in a different relationship, calling into question whether they ought to remain together. In some cases the efforts of the fertile individual to reassure the infertile partner may prevent the fertile partner from acknowledging actual emotions of feeling trapped, angry, or immensely sad at the couple's predicament.

SOURCE: Office of Technology Assessment, 1988.

Some commentators therefore talk of technologies that result in pregnancy versus those that correct any underlying impairment in normal female or male reproductive function. On the other hand, calling infertility a disease and thereby placing it within the medical model is often considered advantageous in terms of acquiring insurance coverage or third-party payments of various types.

The concept of disease has been a bone of contention throughout the history of medicine. Some physicians argue that all disease categories are arbitrary and that the only meaningful entities are patients and laws of physiology and pathology. Others contend that disease terms identify real objects or realities. To avoid this dispute, it is useful to talk about infertility as a clinical problem for which the medical community can sometimes offer a remedy. Using this approach, it is not necessary to ask whether infertility is a disease, and which partner has the disease. As a practical matter, this is important because many cases of infertility can be attributed to subfertility in both partners. This definition includes recognition of the fact that many couples are waiting longer to have babies and expecting to procreate in increasingly shorter periods of time.

PARENTS, CHILDREN, AND FAMILIES

The desire to have children and to become a parent is the reason infertile individuals seek treatment for their infertility or choose adoption. This report is about those who seek diagnosis and treatment of their infertility—people whose motivations for having their own children vary. For some individuals, having children is an important feature of their life plans because of their own experiences as children; their desire to have a link with the future or for emotional or genetic longevity; their desire to love, sustain, and endow specific members of the next generation with tangible and intangible resources; or as an inexplicable part of their love for each other.

For a subset of this group, a genetic tie (i.e., a blood relationship) to their children is extremely important. Some couples seek specific forms of infertility treatment in order that at least one of the parents is genetically related to the child. In addition, for some single men and women, reproductive techniques such as artificial insemination by donor may serve to circumvent not infertility but the lack of a partner of the opposite sex.

Children need nurturing to grow and thrive. A close bond with at least one adult is an essential feature of a healthy childhood, although the specific circumstances surrounding conception and birth can and do vary. Whether or not any variation in a natural event of human fertilization and birth *ought* to occur is the ethical question that is the source of extensive debate about the use of the specific reproductive technologies examined in this report (see ch. 11).

It is not necessary to describe all the current social and demographic changes in families in order to focus on the procreative desires of couples who may vary in lifestyle, social status, or marital configuration. Many argue that the desire to procreate is a family-centered desire by definition. Others argue that the desire to procreate can and should be distinguished from the creation of a family, in order to recognize that a couple can be a family unto itself, that a person might procreate for purposes apart from the creation or enlargement of his or her personal family, or that a person might, through adoption, create a family without procreation. Regardless of how a family is characterized by membership, form, or function, those seeking and providing treatment for infertility share a common interest in creating a new generation.

THE HUMAN REPRODUCTIVE PROCESS

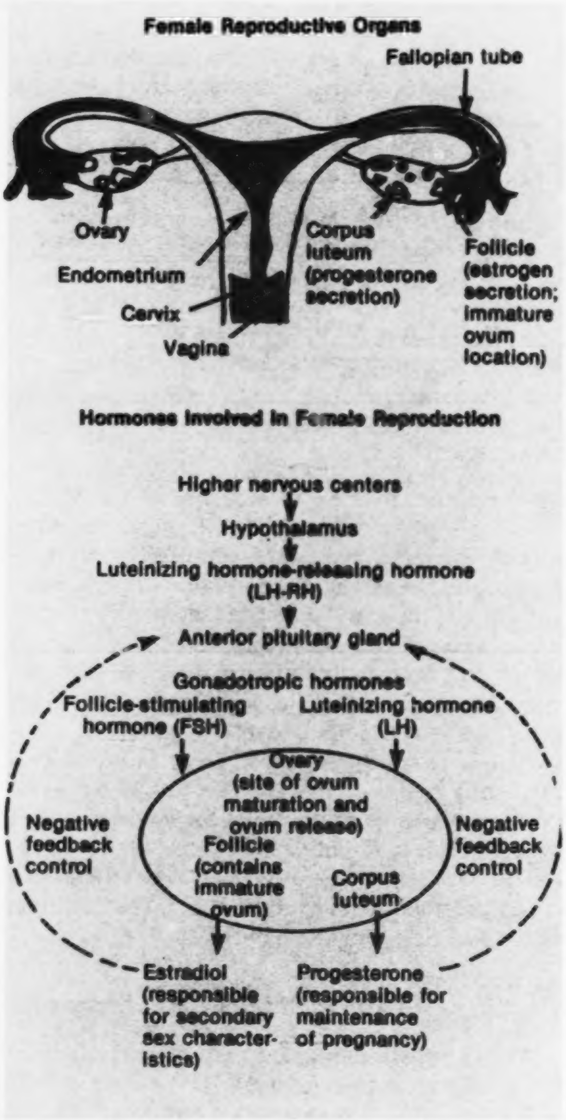
Attempts to create a family typically involve coitus and conception without medical assistance. Single individuals who choose to reproduce and parent alone must use reproductive technologies as a matter of necessity, but for most people, human reproduction is a natural lifecycle event. To understand the anatomic and physiological features of infertility, it is necessary to consider the conditions and processes of normal human reproduction. Many aspects of normal human reproduction are not well understood, and there are areas in which additional research is needed. It is also important to understand the process of fertilization and the early phases of embryonic and fetal development in order to appreciate the technical, legal, and ethical issues involved in the use of reproductive technologies.

Under normal circumstances, fertilization of an egg, implantation of an embryo, and maintenance of pregnancy depend on a series of complex and interrelated events:

- The male must produce an adequate number of normal sperm and must be able to deposit them in the upper vagina at the appropriate time of the female cycle.
- The female must have at least one ovary and her ability to produce eggs (ovulatory mechanisms) must operate within a normal range of levels. Also, hormone levels must be sufficient to stimulate the production of normal cervical mucus near the time of ovulation and to later support implantation of the embryo and maintenance of pregnancy.
- The quality and quantity of cervical mucus must allow sperm to pass into the uterus.
- The oviducts must be open enough to allow fertilization as well as transport of the ovum from ovary to uterus. In addition, functioning tubal ciliary action is also required to assist sperm to travel up the fallopian tubes.
- The uterus must be capable of supporting implantation of the embryo and fetal growth throughout pregnancy (8).

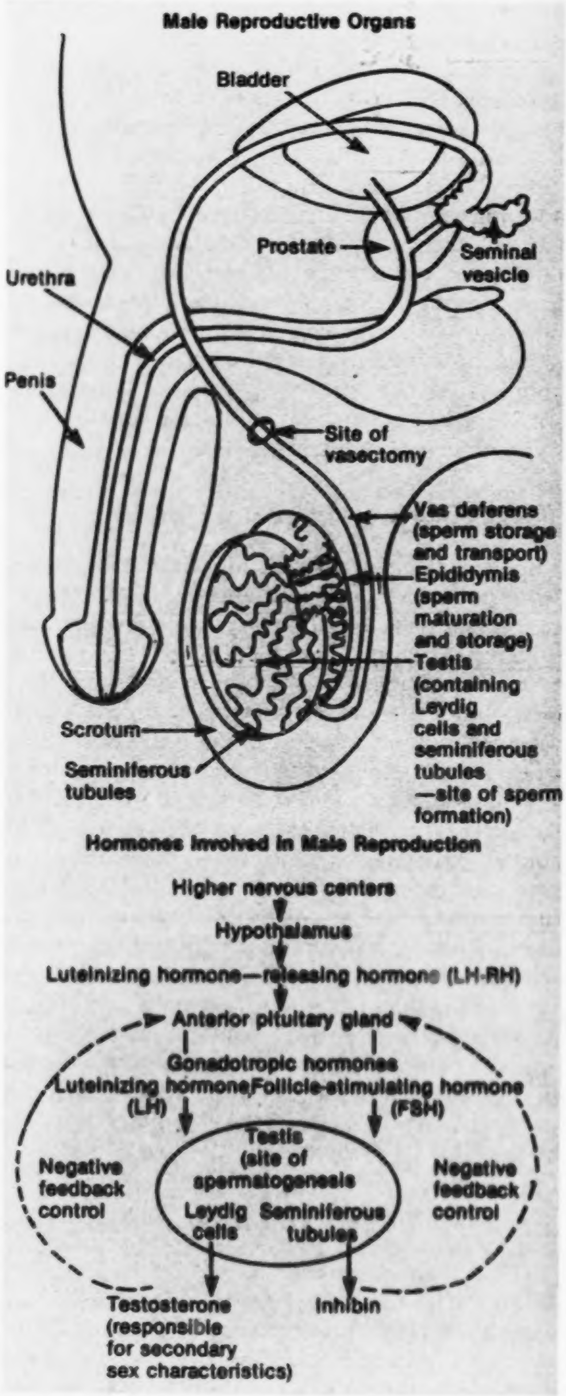
In both men and women, the hypothalamus, an area at the base of the brain, orchestrates the body's reproductive function (see figures 2-1 and 2-2). It receives neural and hormonal input from other parts of the brain and endocrine glands, and responds to these stimuli by secreting luteinizing hormone releasing hormone (LH-RH, also

Figure 2-1.—The Female Reproductive System


Female Reproductive Organs
Fallopian tube
Ovary
Endometrium
Cervix
Vagina
Corpus luteum (progesterone secretion)
Follicle (estrogen secretion; immature ovum location)
Hormones Involved in Female Reproduction
Higher nervous centers
Hypothalamus
Luteinizing hormone-releasing hormone (LH-RH)
Anterior pituitary gland
Gonadotropic hormones
Follicle-stimulating hormone (FSH)
Luteinizing hormone (LH)
Ovary (site of ovum maturation and ovum release)
Follicle (contains immature ovum)
Corpus luteum
Negative feedback control
Negative feedback control
Estradiol (responsible for secondary sex characteristics)
Progesterone (responsible for maintenance of pregnancy)

SOURCE: C. Djerassi, *The Politics of Contraception* (New York: Norton, 1980).

Figure 2-2.—The Male Reproductive System


Male Reproductive Organs
Bladder
Prostate
Seminal vesicle
Urethra
Penis
Site of vasectomy
Vas deferens (sperm storage and transport)
Epididymis (sperm maturation and storage)
Testis (containing Leydig cells and seminiferous tubules —site of sperm formation)
Scrotum
Seminiferous tubules
Hormones Involved in Male Reproduction
Higher nervous centers
Hypothalamus
Luteinizing hormone—releasing hormone (LH-RH)
Anterior pituitary gland
Gonadotropic hormones
Luteinizing hormone (LH)
Follicle-stimulating hormone (FSH)
Testis (site of spermatogenesis
Leydig cells
Seminiferous tubules
Negative feedback control
Negative feedback control
Testosterone (responsible for secondary sex characteristics)
Inhibin

SOURCE: C. Djerassi, *The Politics of Contraception* (New York: Norton, 1980).

known as gonadotropin releasing hormone or Gn-RH) and other hormones. LH-RH acts on the pituitary gland to promote secretion of two hormones, luteinizing hormone (LH) and follicle-stimulating hormone (FSH). Known as gonadotropins, LH and FSH direct hormone and gamete production by the testes and ovaries. The gonads release hormones in response to stimulation by LH and FSH, and these gonadal hormones feed back to modulate the activity of the hypothalamus and pituitary gland (11). A defect at any point in the hypothalamic-pituitary-gonadal axis will interrupt the normal pattern of reciprocal hormone secretion among these organs. It is through the central nervous system that psychological, emotional, sensory, and environmental stimuli can profoundly influence reproductive function.

Sperm Production

Sperm are produced continuously in the testes from puberty throughout adulthood. The process begins with division of sperm cells (spermatogonia), which, in combination with supporting (Sertoli) cells, make up the long, coiled seminiferous tubules that constitute most of the testes. Interspersed Leydig cells produce male hormones (androgens), notably testosterone, that affect both sperm production and male sex characteristics. Sperm production takes about 72 days. The final stages of sperm maturation take place as sperm exit the testis and pass through the long epididymis. Maturation involves changes in motility, metabolism, and morphology. Sperm then leave the body in the semen, a fluid consisting of secretions of the seminal vesicles, prostate, and glands adjacent to the urethra. Ejaculation is a two-part spinal reflex that involves emission, when the semen moves into the urethra, and ejaculation proper, when it is propelled out of the urethra at the time of orgasm.

Egg Production

The female germ cells, called oocytes or ova, are in the two ovaries. They number several million in the fetal stage, are fewer than 1 million at birth, and continue to decline markedly throughout life. Only about 400 to 500 oocytes are actually ovulated during the period of female fertility. In contrast to the continuing renewal of germ cells throughout an adult male's life, no new oocytes are formed after the fetal stage in the female. Usually one oocyte matures each month in a follicle on the ovary's surface, and the follicles also produce estrogen. At ovulation, the follicle ruptures, and the oocyte is picked up by the oviduct and propelled down to the uterus. The ruptured follicle then changes to a yellowish protrusion on the ovary, called the corpus luteum, which begins to secrete another hormone, progesterone, in addition to continued estrogen production. The corpus luteum regresses if pregnancy does not occur. These hormonal changes prepare the uterus for a possible pregnancy, but if pregnancy does not occur, the uterine lining is sloughed off, producing the menstrual flow.

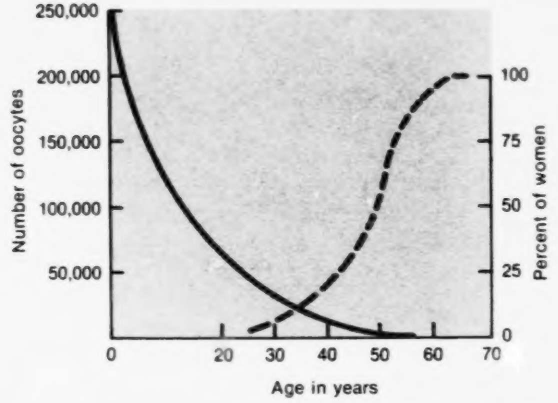
The female menstrual cycle averages 28 days and may range from 26 to 30 days, normally ending with menstrual flow unless pregnancy occurs. Variability in the length of the menstrual cycle typically results from varying duration of the preovulatory, or follicular, phase. It rarely results from variations in the time from ovulation to menstruation—the luteal phase—which usually takes about 14 days.

Menopause, the cessation of menstrual cyclicity, occurs when the ovary is virtually depleted of oocytes, and is marked by diminished production of ovarian estrogens, sudden body temperature fluctuations, and other changes over a longer term. It occurs, on average, at about age 50 (see figure 2-3), but ovulation may occur erratically during the preceding 2- to 10-year period (5). The study of menopause is becoming increasingly important as the number of women age 50 and older (currently half the female population) continues to grow. A woman who is 50 years old today can expect to live to age 89. By the year 2000, women will be spending a greater proportion of their lives in the postmenopausal state due to the continually increasing length of life (10).

Fertilization and Early Development

Human reproduction is characterized by relatively long intervals during which conception is impossible; in fact, fertilization can only take place within about 1 day following ovulation. Fertiliza-

Figure 2-3.—Relation Between Age, Oocyte Number, and Menopause



SOURCE: Adapted from D.R. Mattison, M.S. Nightengale, and K. Shiromizu, "Effects of Toxic Substances on Female Reproduction," *Environmental Health Perspectives* 48:43-52, 1983.

tion usually occurs in the oviduct. When a sperm and egg meet, the sperm penetrates the wall of the egg and the genetic material from the sperm and egg unite. The cell thus formed, containing DNA from both sperm and egg, is called a zygote.

The zygote begins to divide, first into two cells, then into four, then eight, and so on. The mass of cells in the earliest stages is called a conceptus. Cell division, or cleavage, continues as the early embryo passes down the oviduct and develops into a blastocyst through the next 3 or 4 days. The blastocyst is a fluid-filled sphere of cells, resembling a balloon. Most of the cells of the blastocyst are in the outer wall or trophectoderm, which becomes the placenta. The fetus is derived from a small cluster of embryonic cells inside the sphere. The blastocyst starts to implant in the lining of the uterus about 6 to 7 days after ovulation, and at this point is referred to as an embryo. The terms preimplantation embryo and preembryo are sometimes used to describe the mass of dividing cells and the blastocyst up to 14 days after fertilization (1).

During the earliest stages of development, all the cells are more or less equivalent. Once more than 16 cells are present, the trophectoderm cells start to become distinct from the internal cells that ultimately become the fetus. Small and difficult to detect at first, other differences become more pronounced as cell division and growth continue, and they form the foundation for the later differentiation of tissues and organs.

During the second and third weeks after conception—about the time the first menstrual period is missed—the development of the three embryonic layers of cells (endoderm, mesoderm, and ectoderm) occurs as a group of cells called the primitive streak initiates the development of the nervous system. The primitive streak is also the first landmark that reveals the future symmetry of the human body.

The embryonic period takes place between the end of week 2 and weeks 8 to 9 after conception. This is a critical phase of development, during which cell differentiation proceeds at an accelerated pace. During this period, the brain, eyes, heart, upper and lower limbs, and other organs are formed. At 8 to 9 weeks after conception, the embryo makes the transition to a fetus, with most subsequent development taking the form of growth and specialization of organ function, rather than the formation of new organs. Highly complex systems, like the brain and nervous system, continue to develop long after the embryo has become a fetus, and even after birth. Table 2-2 summarizes the timing of embryonic and subsequent fetal development.

Embryonic loss is a normal part of the reproductive process. Only one-quarter to one-third of all embryos conceived become live-born infants. The remainder are lost at some stage between fertilization and the end of pregnancy, for example, prior to implantation. Data on these are hard to obtain, and estimates vary, because the loss of embryos is particularly high in the early stages, before clinical diagnosis of pregnancy is made (see figure 2-4). The time line in this figure represents what is currently conjectured to be the relative amount of reproductive loss among a population of 100 women at various stages of the reproductive cycle.

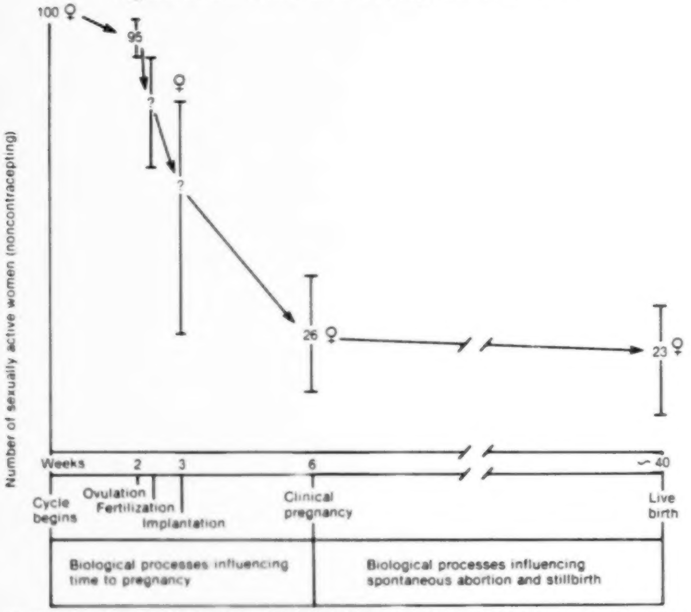
When pregnancy occurs, the ovarian corpus luteum is maintained by another hormone, human chorionic gonadotropin (hCG), secreted by the implanted embryo, and estrogen and progesterone continue to be produced. With the most sensitive laboratory tests, hCG can be detected in blood and urine as early as 6 to 9 days after conception, soon after implantation of the primitive embryo into the uterine endometrium. Measurement of hCG in urine as an indicator of pregnancy is the basis of over-the-counter home pregnancy tests; it is important to note, however, that elevated hCG levels can also be due to other factors, including cancer.

Table 2-2.—Stages of Embryonic and Fetal Development

Period	Time after conception	Stage	Time after conception
Embryo			
"Preembryo," "preimplantation embryo," or "conceptus"	First week	Zygote	1 to 2 days
		Cleavage	2 to 4 days
		Blastocyst	4 to 6 days
		Implantation begins	7 days
Embryonic	2 to 3 weeks	Primitive streak	7 to 8 days
		Gastrula	7 to 8 days
		Neurula	20 days
	3 to 5 weeks	Limb buds	21 to 29 days
		Heart beat	21 to 29 days
		Tail-bud	21 to 29 days
		Complete embryo	35 to 37 days
	6 to 8 weeks	Body definition	42 to 56 days
Fetus	9 to 40 weeks	First fetal	56 to 70 days
		Second fetal	70 to 140 days
		Third fetal	140 to 280 days

SOURCE: Office of Technology Assessment, 1988, adapted from R.H. Blank, *Redefining Human Life: Reproductive Technologies and Social Policy* (Boulder, CO: Westview Press, Inc., 1984).

Figure 2-4.—Time Line of Reproductive Loss



SOURCE: D.D. Baird, A.J. Wilcox, and C.R. Weinberg, "Use of Time to Pregnancy to Study Environmental Exposures," *American Journal of Epidemiology* 124:470-480, 1986.

PUBLIC UNDERSTANDING OF REPRODUCTION

Many Americans are misinformed about key aspects of the relationship between the timing of sex and pregnancy, according to the findings of a 1986 national telephone survey of 802 adults, split equally between men and women (7). (The results of this survey have a 95-percent confidence level, with error due to sampling and other random effects at plus or minus four percentage points.) About one-third of the public said they did not know what the term "ovulation" meant. Only 10 percent of those surveyed accurately described ovulation as the release of an egg from a woman's ovary, while an additional 37 percent gave less specific descriptions that included mention of a woman's egg. One-fourth (26 percent) of those surveyed believed that a woman could become pregnant 10 or more days a month. The largest subgroup to hold this incorrect belief were 18- to 24-year-olds (35 percent).

Americans revealed a great gap in knowledge when asked "How long does the woman's egg live after it's released from her ovary?" Slightly more than half (51 percent) said they did not know. A higher percentage of women (56 percent) than men (47 percent) said "don't know" in response to this question of the female reproductive system. The fertile life of the human egg is believed by scientists to be an average of about 24 hours.

Half (53 percent) of those surveyed believed that on average it takes 3 months or less of trying for a couple to conceive; the actual average is at least 4 months. Perhaps as a result of this underestimation of the time it takes the average couple to conceive, half (53 percent) of those surveyed felt a couple should seek medical advice if conception did not occur after 6 months or less of trying. An additional 28 percent said that medical advice should be sought after 6 to 12 months of trying (7).

Overall, the study found that Americans exhibit a definite lack of knowledge about many of the facts relating to fertility and reproduction. The low level of knowledge of the ovulation process as well as poor understanding of the basic facts about the male and female reproductive systems were generally consistent across demographic subgroups (7). These facets of the public's misunderstanding and lack of information about human reproduction are an important aspect of the social context of this OTA study.

THE OTA STUDY

With this report, OTA assesses what it means in the late 1980s for some couples to conceive and form a family. Couples unable to conceive a child without assistance and those unable to conceive at all are faced with an array of technical and social means to assist reproduction. These procedures—some involving high technology and others involving ordinary technology—raise a host of novel issues in medicine, ethics, law, and economics. At times, they even require a new vocabulary (see box 2-B). The 13 chapters that follow describe methods of assisted conception and provide a comprehensive examination of the issues raised by their use.

Beyond the concerns of an individual couple lies perhaps the most difficult aspect of infertility prevention and treatment for public policymakers: the question of the government's role with respect to assisted conception. In addressing this issue, policymakers are subjecting to public discussion sexual topics generally consigned to private conversation. Such discussion must be viewed in the context of a sizable level of public ignorance about human reproductive biology. A series of policy issues and associated options for congressional action are presented in this report in order to address the concerns of policymakers.

Box 2-B.—New Conceptions, New Vocabulary

Expectations and obligations created by the use of noncoital reproductive techniques are shared among the sperm or ovum donors, gestational mother, intended rearing parents, physicians, attorneys, commercial brokers, and resulting child. In many ways, the English language is inadequate to express all of these possible relationships. For example, the term "sperm donor" can be misleading when in fact a man sells his sperm; "sperm vendor" would be more accurate, but does not match common parlance.

"Surrogate mother" is a troubling term because of possible confusion over usage. The popular press appears to use the term to cover both women who carry to term an embryo to which they are genetically unrelated and women who are artificially inseminated with the sperm of a man who intends to be the rearing parent of the resulting child when the women themselves will not be rearing parents. The legal literature uses the term to refer almost exclusively to the latter situation, which in fact is far more common. "Surrogate gestational mother" is the term used in legal parlance to cover the former situation.

An additional problem stems from the possibly prejudicial use of the term "surrogate" in the context of a woman who is artificially inseminated (i.e., who is the genetic and gestational mother of the child). This genetic and gestational relationship embodies the traditional definition of "mother." A woman's prior agreement to relinquish a child does not diminish this fact, as can be seen in the context of prebirth adoption arrangements. The term "surrogate mother" may imply that the surrogate in this situation is somewhat less than a real mother. This is not true biologically and has not yet been determined legally.

For the purposes of this report, a woman with a genetic relationship to the child is called the "genetic mother" or "ovum donor," as appropriate. The woman who is both genetically and gestationally the parent of a child is called the "mother." In the interests of clarity, she may be referred to as the "surrogate mother" when describing surrogacy arrangements. If a woman carries to term a child to whom she is genetically unrelated, she is referred to as the "gestational mother"; again, in the interests of clarity she may be referred to as the "surrogate gestational mother" in the context of surrogacy arrangements. Regardless of their biological relation to a child, the persons who intend to raise the child are referred to as the "intended rearing parents."

SOURCE: Office of Technology Assessment, 1988.

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Chapter 3

Demography of Infertility

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Chapter 3

Demography of Infertility

Epidemiological studies of infertility attempt to define variations in reproductive impairments for men and women of different ages, races, and parities (the number of children born to a woman), to illuminate historical trends, and to identify possible contributory factors. Three national demographic surveys—the 1965 National Fertility Study (NFS); the 1976 National Survey of Family Growth (NSFG), Cycle II; and the 1982 National Survey of Family Growth, Cycle III—provide data on infertility in the United States. All three surveys describe couples with married women in their childbearing years (defined as age 15 to 44) in the continental United States; the 1982 survey also contains information on never-married women of the same ages.

Cycle IV of the National Survey of Family Growth began in early 1988. The baseline survey is being repeated, and new questions have been added. Portions of this survey are directly related to infertility (see box 3-A). Preliminary data will be published in 1989, with more reports to follow in 1990 and subsequently (19). Cycle V of the NSFG is scheduled for 1992.

Other sources of data concerning the availability and use of infertility services, such as a series of surveys by the Alan Guttmacher Institute looking at private physicians and family planning organizations, are discussed in this chapter. In conjunction with the NSFG, these surveys yield a description of infertility service providers.

NSFG DATA

In 1982, the NSFG surveyed a sample of 7,969 women of reproductive age, of whom 3,551 were married. The data for each woman are multiplied by the number of women she represents in the population, so the 7,969 women interviewed represent the 54 million women aged 15 to 44 in the United States. Thus, the data in this chapter represent national estimates (21).

The questions were addressed only to women, so in married couples the wife spoke for herself and her husband. Data from the surveys thus measure infertility of the couple. They do not distinguish male and female factors related to infertility. This chapter refers to the "couple" instead of the "wife" when presenting the data. Similar data for men do not exist, as the Government collects little information on the reproductive health of men.

Definitions

A couple's reproductive ability is categorized in three ways by demographers: surgically sterile (impossible to have a baby, whether by choice or not); impaired fecundity (nonsurgically sterile or difficult or dangerous to have a baby); and fecund (no known physical problem). Many couples classified as fecund actually have unknown fecundity—those using contraception, for example.

Fecundity refers to the potential of a couple to reproduce. The medical profession prefers the term fertility, which refers to actual conception rates. Infertility is a medical term indicating 12 months of unprotected intercourse without conception (see ch. 2). Thus, infertility does not indicate sterility but instead highlights a population that has trouble conceiving and may need medical assistance.

For this report, the term infertility rather than impaired fecundity is used. The percentage of infertile couples is slightly less than the percentage with impaired fecundity, as the latter category includes couples for whom it is difficult or dangerous for the woman to maintain a pregnancy (a category that includes miscarriage). Infertility refers only to couples who have tried to conceive and failed, not to couples who choose not to attempt conception (whether for medical or social reasons).

Box 3-A. National Survey of Family Growth, 1988

Cycle IV of the National Survey of Family Growth, conducted by the National Center for Health Statistics between January 1988 and July 1988, asks approximately 10,600 women about their sex education, pregnancy history, ability to bear children and future plans, use of family planning and infertility services, and socioeconomic data.

The chief questions regarding infertility asked by the 1988 NSFG include the following (questions from previous surveys are similar):

- Some women find it physically impossible to have (more) children. As far as you know, is it physically possible or impossible for you, yourself to conceive a(nother) baby, that is, to get pregnant (again)?
- What about your (husband/partner)? Is it physically possible or impossible for him to father a(nother) child?
- What is the reason that it is physically impossible for you (and your husband/partner) to have a(nother) baby?
- Some people are able to have a(nother) baby, but have difficulty getting pregnant or holding onto the baby. As far as you know, is there any problem or difficulty for you (and your husband/partner) to conceive or deliver a(nother) baby (after this pregnancy)?
- What is the reason it would be difficult for you to have a(nother) baby?
- Have you (or your husband/partner) ever been to a doctor or clinic to talk about ways to help you become pregnant?
- What kinds of medical treatment or advice have you (or your husband/partner) had to help you (become pregnant/prevent miscarriage)?
- To which of the places [listed] did you (or your husband/partner) go for that visit?
- After you (or your husband/partner) went for this treatment or advice, were you able to have a baby?
- Have you (or your husband/partner) had an operation, or more than one operation, that would prevent you from conceiving a(nother) baby (together)?
- What kind of operation, or operations, did you (or your husband/partner) have that would prevent you from conceiving a(nother) baby?
- Before the (first) operation was it impossible for you (and your husband/partner) to conceive a(nother) baby, was it difficult, or did you have no problem at all?
- Have you (or your husband/partner) ever had surgery or treatment to reverse a sterilization operation?
- Have you ever been treated in a doctor's office, clinic, or emergency room for an infection in your fallopian tubes, womb, or ovaries, also called a pelvic infection, pelvic inflammatory disease, or PID?
- How many times have you been treated for PID?
- Have you ever heard of chlamydia?
- Has a doctor ever told you that you have chlamydia?
- Has a doctor ever told you that you have gonorrhea?
- Has a doctor ever told you that you have endometriosis?

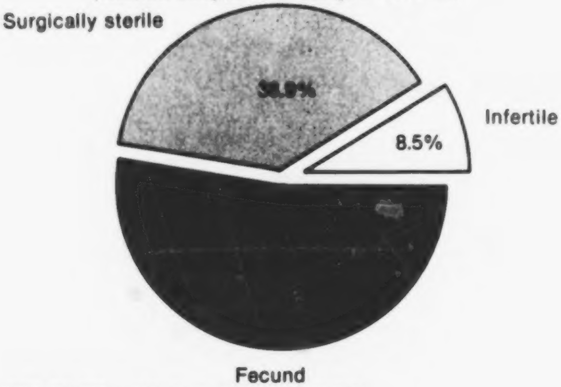
SOURCE: U.S. Department of Health and Human Services, Public Health Service, National Center for Health Statistics, *National Survey of Family Growth: Cycle IV* (Washington, DC: 1988).

Survey Results

In 1982, 8.5 percent (2.4 million) of married couples were infertile, 38.9 percent (11.0 million) were surgically sterile, and 52.6 percent (14.8 million) were fecund (see figure 3-1). **The number of infertile couples declined from 3.0 million in 1965 to 2.4 million in 1982. More importantly, primary infertility (childlessness) doubled, from 500,000 in 1965 to 1 million in 1982, while secondary infertility (in which couples have at least one biological child) declined, from 2.5 million in 1965 to 1.4 million in 1982** (see table 3-1) (18).

The increase in primary infertility can be explained partly by the fact that more couples are attempting to have children, as members of the baby-boom generation reach their childbearing

Figure 3-1.—Infertility Status, 1982
(married couples, wives aged 15 to 44)



SOURCE: Office of Technology Assessment, 1988.

years and try to have their first baby. The decrease in secondary infertility can be explained by the increase in voluntary surgical sterilization (from 15.8 percent in 1965 to 38.9 percent in 1982). This increase was due solely to the increase in sterilization for contraceptive purposes; the change in noncontraceptive sterilization was slight (18,22). Contraceptive sterilization masks a number of women who might otherwise discover that they were infertile, especially at ages 30 and older (22).

Although the percentage of couples infertile appears to have decreased over the past two decades (from 11.2 percent in 1965 to 8.5 percent in 1982), this drop is entirely due to the rise in surgical sterilization. **Excluding the surgically sterile, the percentage of couples infertile has changed only slightly, rising from 13.3 to 13.9 percent** (18).

Black couples are more likely than white couples to be infertile; in 1982, the risk of infertility for black couples was 1.5 times that for white couples (26). Many possible explanations for these higher rates have been presented, although no data exist on the subject:

- the higher incidence of sexually transmitted diseases (STDs), as STDs account for an estimated 30 percent of infertility in some high-risk populations in the United States (26) and may account for up to 20 percent of infertility overall (4) (the difference in rates of STD between blacks and whites reflects the difference in other relevant demographic characteristics, such as urban dwelling, rather than actual racial differences (7));
- the greater use of intrauterine devices (which can increase the likelihood of pelvic inflammatory disease);
- environmental factors, such as occupational hazards affecting reproduction (30); and
- complications or infections following childbirth or abortion (25).

Couples with wives having less than a high school education were also more likely to be infertile (2,16).

Within age groups, the only significant change over time occurred in those 20 to 24

Table 3-1. Infertile Couples, 1965 and 1982

	All		Excluding surgically sterile	
Couples	1965	1982	1965	1982
Number of couples (millions)[a]				
Total	26.5	28.2	22.3	17.2
Childless	3.5	5.1	3.2	4.6
1 or more children	23.0	23.1	19.1	12.6
Number infertile (millions)				
Total	3.0	2.4	3.0	2.4
Childless	0.5	1.0	0.5	1.0
1 or more children	2.5	1.4	2.5	1.4
Percent infertile				
Total	11.2	8.5	13.3	13.9
Childless	14.5	19.6	15.6	21.8
1 or more children	10.9	6.1	13.1	11.1

[a] Wives 15 to 44 years old.

SOURCE: Adapted from W.D. Mosher, "Infertility: Why Business Is Booming," *American Demographics* 9:42-43, 1987.

years old. In 1965, 4 percent of this group were infertile; by 1982, 11 percent were infertile (17,26). This increase may be linked to the tripled gonorrhea rate of this age group between 1960 and 1977 (18), as well as to the factors mentioned previously regarding the higher rates of infertility in black couples. This particular group is important, as one in three births in the United States occurs to women 20 to 24 (22).

Data from the NSFG indicate that infertility increases with age: **Excluding the surgically sterile, 14 percent of married couples with wives aged 30 to 34 are infertile, while 25 percent of couples with wives aged 35 to 39 are infertile** (see table 3-2) (18). To date, the influence of age on female fertility has been examined more closely than has its influence on male fertility. Although viable sperm production does decline with age in humans (13), the effect of this on fertility has not been determined (23).

In recent years there has been controversy in the scientific and popular literature over the rate at which a woman's fertility decreases with age (3,8,9,14,15,27). Studies have attempted to control for variables such as frequency of intercourse (which is known to decrease as the length of marriage increases) and to examine societies that have little evidence of deliberate fertility control. The results are varied and widely debated, but all seem to indicate that **female fertility does decrease somewhat before age 35 and significantly more after age 35**. The disagreement focuses primarily on the extent of the decrease when a woman reaches age 30. Most of the available statistics are more useful for indicating the number and types of women who are likely to need and use infertility services than for estimating a woman's decreased fertility with age and the effects of delayed childbearing (15).

Survey Limitations

Available survey data may misrepresent the true numbers of infertile couples. First, the boundary of 1 year for the definition of infertility is somewhat arbitrary; many couples classified as infertile after 1 year will conceive later without medical assistance (15). In an unrandomized observational study of 1,145 infertile couples, 41 percent of those whose infertility problems were treated later conceived, while 35 percent of those untreated also became pregnant (3). However, the 1-year limit has both a practical and a theoretical justification. Practically, the NFS and NSFG are the only national surveys to examine infertility status, and they use the 1-year definition. Most physicians use this definition as well (20). Furthermore, if an average woman with no infertility problems has an approximate monthly probability of conception of 20 percent (0.2 as a proportion), 93 percent of all women would theoretically conceive after 1 year of unprotected intercourse (12).

Second, the surveys did not directly ask whether the respondent had ever tried to become pregnant (22), meaning that women who have always used contraception, never had intercourse, or never tried to become pregnant were assumed to be fertile. A number of potentially infertile couples may be hidden in the groups of surgically sterilized couples and couples using contraception. The authors corrected for one problem by excluding the surgically sterile from some data and thus removing the effects of the sharp rise in surgical sterilization between 1965 and 1982. However, couples using contraception who have not been proved fertile are included in the category "fecund," which may lead to an underestimation of the extent of infertility.

Third, the surveys refer to married couples with wives aged 15 to 44. As a result, unmarried men and women are not included in these figures (except in the 1982 data, when unmarried women were also surveyed). Excluding unmarried couples may have resulted in an underestimate of the absolute number of infertile couples. Finally, the data only permit a guess at the populations at increased risk for infertility.

Table 3-2. Infertility and Age, 1965 and 1982 (percent)[a]

Age of wife	1965	1982
15 to 19	0.6	2.1
20 to 24	3.6	10.6
25 to 29	7.2	8.7
30 to 34	14.0	13.6
35 to 39	18.4	24.6
40 to 44	27.7	27.2
Total, 15 to 44	13.3	13.9

[a] Percent of married couples excluding those surgically sterilized. Data are based on samples. The only statistically significant change between 1965 and 1982 is the increase at age 20 to 24.

SOURCE: W.D. Mosher, "Infertility: Why Business Is Booming," *American Demographics* 9:42-43, 1987.

INFERTILITY SERVICES

The National Survey of Family Growth provides data on the infertility services most frequently received by the population. Overall, the 1982 survey reports the following services as most popular among female respondents: advice on the timing of intercourse (19 percent); general health advice (18 percent); drugs to induce ovulation (17 percent); other advice (15 percent); and tests (12 percent). The most frequently reported infertility service for husbands was a sperm count (29).

Who Provides Infertility Services?

Providers of medical infertility treatment services typically fall into three categories:

- primary care physicians,
- specialized infertility centers that offer in vitro fertilization (IVF), and
- other centers offering infertility treatment.

In general, primary care physicians appear to be the front-line providers of infertility treatment services. According to one survey, patients seeking such services from primary care physicians are served mainly by obstetrician/gynecologists (66 percent), followed by urologists (22 percent) (1). Most patients first discuss their concerns with either an obstetrician/gynecologist (for a female) or a urologist (for a male) or both.

Infertility care is also provided by other physicians. The Alan Guttmacher Institute (AGI) surveyed a sample of the 100,000 private physicians in four specialties, and estimated that some 45 percent of them provide infertility care (1). These 45,600 physicians include 17,500 general/family practitioners, 1,400 surgeons, 20,600 obstetrician/gynecologists, and 6,100 urologists (1). The large proportion of general and family practitioners is explained by the large number of them in practice (about twice as many as obstetrician/gynecologists) as well as by their widespread geographical distribution (24).

Most obstetrician/gynecologists (96 percent) and urologists (92 percent) provide at least some infertility services as part of their private office practice, although this may not be their area of specialization or greatest expertise. General/family practitioners (35 percent) and general surgeons (6 percent) were less likely to offer any infertility services. Physicians practicing in the north central and western regions of the country, as well as younger physicians, are slightly more likely than other physicians to treat infertility (1).

Although virtually no private physicians provide all infertility treatment services, the vast majority of obstetrician/gynecologists provide basic diagnostic services, as well as a substantial number of diagnostic/treatment services, including clomiphene (91 percent), hysterosalpingograms (89 percent), and laparoscopies (85 percent). Similarly, 83 percent of urologists provide basic physical exams and counseling, as well as semen analyses (1). Artificial insemination is also frequently arranged with private physicians (28).

Most physicians who provide infertility services refer patients elsewhere when necessary, usually to another physician (1). However, for female patients, obstetrician/gynecologists are more likely than general practitioners to make referrals to infertility centers or clinics rather than to other physicians. This may be due to the relatively complex services that such physicians already provide for women, and the need for specialty referrals.

Estimates of the number of patients treated privately for infertility vary widely. Data from the 1980-81 National Ambulatory Medical Care Survey show that the number of office visits, by the principal diagnosis of infertility, to physicians practicing obstetrics and gynecology averaged 556,000 annually (6). One analysis of this data estimated that between 111,200 and 161,240 new infertility cases are diagnosed each year and that between 200,000 and 300,000 patients are treated for infertility annually (6).

The AGI study estimates that private physicians in the United States see 1.55 million patients annually for infertility; this may include patients who see more than one physician, as well as both partners in a couple. The National Survey of Family Growth estimated that 1 million to 1.2 million couples consulted a physician about infertility problems in 1981; about 80 percent of the consults (i.e., 800,000 to 950,000) were sought from private physicians (1).

The second category of infertility service providers, IVF/infertility centers, is discussed in detail in chapter 8. In 1987, there were 169 clinics in the United States offering IVF or gamete intrafallopian transfer (see app. A), but proficiency in these techniques varied widely. Most centers offer a variety of the well-established infertility diagnostic and treatment services, except male microsurgery and artificial insemination. Many clinics are more oriented toward the treatment of female infertility than male infertility.

The last category of providers includes family planning agencies in hospitals, health departments, and Planned Parenthood facilities. Under the guidelines to Title X of the Public Health Service Act, family planning service grantees must make basic infertility services available to clients upon request. The AGI survey estimated that 70 percent of family planning agencies, or 1,712 agencies nationwide (compared with 45,000 private physicians), provide at least some basic infertility services (e.g., physical exams, counseling, infection investigation, and basal body temperature instruction) (1). However, at least half the family planning agencies responding to this question said that they see fewer than 10 infertility patients per year; lack of demand, lack of appropriately trained staff and lab facilities, and the high costs of infertility services are among the reasons that this type of agency accounts for a minimal amount of infertility services.

The category of "other" infertility service providers also includes an unknown (although probably small) number of centers that specialize in infertility services but that do not provide IVF or gamete intrafallopian transfer.

Who Seeks Infertility Services?

In 1982, couples with primary infertility were twice as likely as couples with secondary infertility to seek infertility services; approximately half of the women with primary infertility stated that they or their husbands had ever sought services, compared with approximately one-quarter of the women with secondary infertility (see table 3-3) (10). Overall, 31.4 percent of infertile married couples had ever looked for infertility services. Couples with older wives were more likely to have used such services (11).

Table 3-3. Use of Services for Infertility, 1982 (percent)

Infertility status	Women who ever sought services[a]
All infertile women	31.4
Women with primary infertility	51.2
Women with secondary infertility ...	22.4

[a] Wives 15 to 44 years old.

SOURCE: Adapted from M.B. Hirsch and W.D. Mosher, "Characteristics of Infertile Women in the United States and Their Use of Infertility Services," *Fertility and Sterility* 47:618-625, 1987.

Although black couples are more likely to be infertile, a larger proportion of white couples had requested medical evaluation of their infertility in the 3 years before the NSFG (11). In 1982, 18.6 percent of ever-married white women had used services for infertility, compared with 13.5 percent of ever-married black women (11). (The category "ever-married women" is larger than the category "currently married women," used previously in this report. However, the number of divorced or separated women seeking infertility services is likely to be relatively small.)

Based on the 1982 NSFG, it is estimated that **1 million ever-married women in the United States stated in 1982 that they or their husbands had used infertility services in the past year** (11). In the same year, approximately 6 million (or one in six) ever-married women 15 to 44 years old stated that they or their husbands had used such services at some point during their lives.

The NSFG estimates of the number of infertile couples probably underestimate the number of couples who might seek treatment for infertility. The category "surgically sterile" hides a number of couples who would have discovered infertility problems had they not been sterilized. It also includes a number of individuals who may have changed their minds about undergoing contraceptive sterilization. If the couple desires a future birth, they may seek infertility services to overcome their self-imposed sterility. Second, couples who are unable to have a live birth or who choose not to conceive because it is difficult or dangerous for the woman to carry a pregnancy to term are not included in the definition of infertility;

however, they might be candidates for some type of infertility service (e.g., surrogate motherhood).

Increased Use of Services

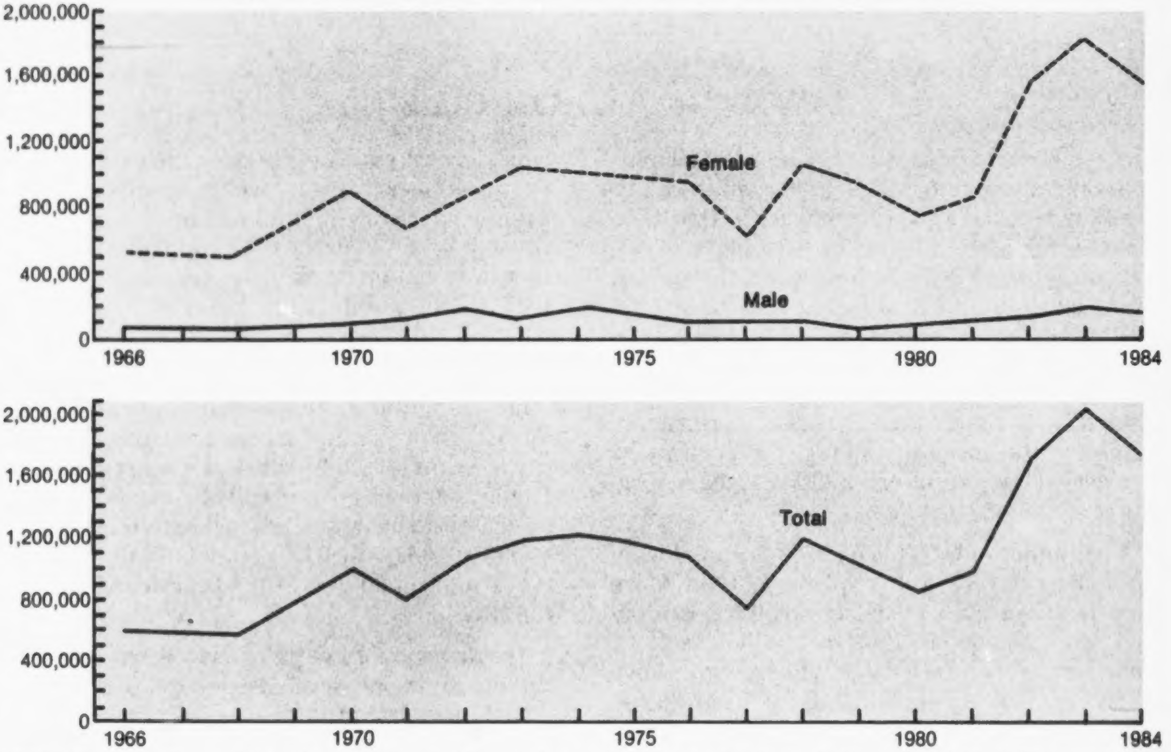
Although the percentage of American couples faced with infertility does not appear to have grown, popular concern about infertility has increased, as has the demand for infertility services.

The greater demand for infertility services is well documented. The estimated number of visits to private physicians' offices for consultation related to infertility rose from about 600,000 in 1968 to over 900,000 in 1972 to about 2 million in 1983, then dropped to 1.6 million in 1984 (see figure 3-2).

Although the 20 to 24 year olds, for whom infertility actually did increase, are an important group, the growth of infertility among them is not significant enough to account for the increased demand for infertility services. A number of factors have contributed to an increase in demand despite the absence of an overall increase in infertility rates (see table 3-4):

- The absolute number of couples with primary infertility has risen with the aging of the baby-boom generation; with delayed childbearing, which exposes more couples to higher age-specific infertility rates; with the use of oral contraceptives (which often delay conception, thus inflating numbers of infertile couples); and with the tendency of couples to classify themselves as infertile more quickly (due to a desire to condense childbearing into a shorter interval, for example).
- The proportion of couples seeking treatment has risen due to the decreased number of infants available for adoption; the increased awareness of various treatments available for

Figure 3-2.—Total Visits to Private Physicians for Infertility, 1966-84



SOURCE: W. Cates, Jr., Director, Division of Sexually Transmitted Diseases, Center for Prevention Services, Centers for Disease Control, Atlanta, GA, personal communication, June 23, 1987.

Table 3-4.—Some Causes of Increasing Requests for Infertility Services in the 1980s

More couples with primary infertility	Increasing proportion of infertile couples seeking care	Increasing number of physicians providing infertility services	More conducive social milieu	Evolution of new reproductive technologies
• Aging of the baby-boom generation • Delayed childbearing; more people in higher risk age groups • Childbearing condensed into shorter intervals • Delayed conception due to prior use of oral contraceptives	• Decreased supply of infants available for adoption • Heightened expectations • Larger number of people in higher income brackets with infertility problems • Larger percent of infertile couples are primarily infertile	• Greater demand from private patients • More sophisticated diagnosis and treatment • At least 169 sites in the United States offering IVF or GIFT	• Baby-boom generation expects to control their own fertility • Profamily movement • Increased discussion of sexual matters due to the AIDS epidemic • Extensive media coverage	• IVF • GIFT • Artificial insemination • Surrogate motherhood • Cryopreservation

SOURCE: Adapted from S.O. Aral and W. Cates, Jr., "The Increasing Concern With Infertility: Why Now?" *Journal of the American Medical Association* 250:2327-2331, 1983.

infertility; a greater proportion of couples in higher socioeconomic brackets with infertility problems; and a larger number of couples with primary infertility.

- Increasing numbers of physicians are providing infertility services.
- The profamily movement has defined infertility as a major health problem. Sexual matters are generally discussed more openly as a result of the AIDS epidemic.
- Novel reproductive techniques used to treat infertility have evolved.

Overall, the increase in requested infertility services has likely surpassed any actual increase in the overall percentage of couples with infertility.

SUMMARY AND CONCLUSIONS

In 1982, approximately 8.5 percent of all married couples were infertile, 38.9 percent were surgically sterile, and 52.6 percent were fecund. Generally, black couples, couples with older wives, and couples with the wife having less than a high school education were at higher risk for infertility. The percentage of married couples who were infertile decreased significantly between 1965 and 1982, although this decrease can largely be explained by the increase in surgical sterilization. Excluding the surgically sterile, the percentage of married couples infertile did not change significantly.

The number of infertile couples declined from 3.0 million in 1965 to 2.4 million in 1982. More importantly, primary infertility (childlessness) doubled, from 500,000 in 1965 to 1 million in 1982, while secondary infertility (in which couples have at least one biological child) declined, from 2.5 million in 1965 to 1.4 million in 1982.

Female fertility decreases somewhat before age 35 and significantly more after age 35. There is considerable controversy over the extent of the decrease, especially between ages 30 and 35. Another cycle of the National Survey of Family Growth began in early 1988 and will collect further information on all these trends; preliminary data will be published in late 1989.

Infertility treatment is provided by primary care physicians, specialized infertility centers, and other centers (e.g., family planning clinics). Primary care physicians appear to be the front-line providers of infertility services. Couples using infertility services are more likely to have primary infertility, to be white, and to have wives who are older. In 1982 only 31.4 percent of infertile married couples had ever sought services for infertility.

The demand for infertility services has increased rapidly in recent years, despite the fact that the actual incidence of infertility has not. The number of office visits to private physicians for infertility services rose from about 600,000 in 1968 to some 1.6 million in 1984.

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Chapter 4

Factors Contributing to Infertility

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Chapter 4

Factors Contributing to Infertility

Current knowledge of the factors that contribute to infertility is limited. Classification of infertility due to any one condition is misleading, as contributing factors are often multiple and the boundaries between them are not clear. Those covered in this chapter do not always fit neatly into the categories in which they are discussed; for example, there may be a genetic component to endometriosis, yet the two are presented as separate factors contributing to infertility.

Another problem arises when examining reasons for infertility. Should the underlying condition, such as a sexually transmitted disease (STD), or the mechanism by which it leads to infertility, such as tubal damage, be called the contributing factor? For prevention, the underlying condition is the important factor, as the disease can potentially be avoided. For treatment, however, the mechanism is often more important; whatever damage it has caused must be repaired or circumvented for pregnancy to occur.

Sometimes the mechanism by which a given condition results in infertility is not clear; sometimes it is not clear what condition underlies a functional impairment. This chapter presents the current knowledge of factors contributing to infertility, whether they be an underlying condition, its mechanism of action, or both.

INFECTION

Sexually Transmitted Diseases

Sexually transmitted diseases are the third most common infectious diseases in the United States, after the common cold and influenza. They account for an estimated 20 percent of infertility in selected populations (29). Furthermore, they are usually difficult to diagnose, especially in women. STDs are most damaging to women and children (excluding acquired immunodeficiency syndrome, which is equally damaging to anyone who contracts it, regardless of age or sex), although they affect males as well. The three STDs that most affect fertility are gonorrhea, chlamydial infection, and mycoplasmal infection.

Gonorrhea is an infection caused by the bacteria *Neisseria gonorrhoeae*. More than 760,000 cases were reported in 1987 (33). In women, if the infection is not treated it can spread to the uterus and fallopian tubes, causing pelvic inflammatory disease (PID), which can lead to infertility. In men, bacteria can directly affect semen quality by inducing phagocytosis or stimulating production of antibodies (113). Also, untreated genital infection can cause infertility in men by creating inflammation or blockage in the upper reproductive tract. For example, untreated infection can spread to the epididymis, causing epididymitis. Epididymitis can impair fertility during the infection as well as cause scarring that can partially or completely block sperm transport. Reports from Nigeria and from the preantibiotic era indicate that various genital tract infection syndromes are associated with male infertility (2,8,126). However, followup fertility studies of men with documented inflammation of the urethra, epididymis, and/or testis or with accessory gland infection are not available, so knowledge of the actual effect of STDs on male fertility is scant.

Infection caused by *Chlamydia trachomatis* is the most common STD in the United States today, infecting approximately 4 million people in 1985 (30,174). In women, chlamydial infection accounts for one-quarter to one-half of the PID cases seen each year (30). In men, chlamydial infections cause approximately half the reported cases of nongonococcal urethritis and also half the estimated 500,000 cases of acute epididymitis seen annually (30). In both men and women, chlamydial infection is more difficult to detect than gonococcal infection, and thus may go untreated, resulting in more harm (149).

Considerable controversy surrounds another group of sexually transmitted organisms commonly found in the male and female reproductive tracts—mycoplasmas (24,76,82,149). Because mycoplasmal infections often coincide with other infections, it is difficult to determine whether the mycoplasmas themselves actually cause tissue damage (149).

Among sexually active women, a major cause of impaired fertility is damage to the fallopian tubes, and possibly the ovaries, caused by pelvic inflammatory disease (28). If untreated, the bacteria that cause gonorrhea, chlamydial infection, and other infections may ascend from the lower genital tract through the endometrium (causing endometritis) to the fallopian tubes (salpingitis), and possibly to the ovaries (oophoritis) and pelvic peritoneum (peritonitis). Reduced fertility due to PID probably stems primarily from physical damage to the fallopian tubes (28,49,175,185): Peritubal (around the tube) adhesions decrease tubal mobility, which is essential for passage of the ovulated egg. Blocked or deformed tubes can severely obstruct the movement of both ova and sperm that is necessary for fertilization. Bacterial products or byproducts of inflammation can also cause impaired function of the oviduct.

The majority of bacterial-based PID results from one or more sexually transmitted diseases; *N. gonorrhoeae* and *C. trachomatis* together account for more than two-thirds of the 1 million cases of PID seen each year (3). In 1982 approximately 14 percent of women between ages 15 and 44 reported being treated at least once for PID during their lifetime (5). According to two estimates, a woman with a gonococcal or chlamydial infection has a 10-percent risk of developing PID, and from 10 to 20 percent of the approximately 1 million women with PID each year will become infertile (140,174). The likelihood of infertility increases dramatically with increasing episodes of PID, from an estimated 11.4 percent after one episode to between 54.3 and 75 percent after three episodes (183,185). The likelihood of infertility also increases with the severity of the PID (17,185).

Although more common in developing countries than industrial ones, other genital tract infections can lead to PID. Infections after birth, cesarean sections, abortions, and many other obstetric or gynecologic procedures can cause tubal damage. Whether these infections actually lead to infertility is subject to some controversy (85,163).

Damaged or blocked tubes resulting from PID may lead to another complication, ectopic pregnancy. An ectopic pregnancy is one that occurs outside of the uterus, usually in a fallopian tube, because the fertilized egg cannot travel to the uterus through the damaged or blocked tube. PID is not the only cause of ectopic pregnancy; congenital tubal malformation and tubal ligation are other possible causes. The magnitude of PID's influence on the increasing incidence of ectopic pregnancy is controversial (7,36). From 1970 through 1983, the number of ectopic pregnancies in the United States quadrupled (31), possibly as a consequence of the increased occurrence of PID (102,176). Some estimates indicate that 30 to 60 percent of ectopic pregnancies are associated with evidence of PID (176,178). The frequency of tubal pregnancy increases sixfold to tenfold following a documented episode of PID (178,185). The likelihood of infertility in turn increases after an ectopic pregnancy (119).

Douching may be related to both ectopic pregnancy and PID. One case-control study suggested that women who douche weekly have a significantly higher risk of ectopic pregnancy than women who never douche (37). It has also been proposed that douching may be a risk factor for PID (121).

Other Infectious Diseases

Past studies suggest that 30 percent of men with bilateral postpubertal mumps orchitis develop azoospermia (25). Approximately 2,982 men in the United States contracted mumps in 1985, with 725 of them being postpubertal cases (32). Mumps does not appear to be a major contributor to male infertility here, but rates of the disease have increased in recent years (27) and the number of cases doubled between 1986 and 1987 (33).

HORMONAL DISTURBANCE

Polycystic Ovarian Disease

Researchers disagree on the cause of the malfunction in the hormonal system that leads to polycystic ovarian disease, although many theories implicating the hypothalamus, the pituitary, the ovaries, and the adrenals have been suggested (87). However, the result of the disease—ovaries clogged with cysts and few or no ovulations each year—clearly undermines fertility (16,61).

Cervical Factors

The complex change of the cervical mucus of the female at the time of ovulation is under hormonal control. The changes assist the survival and transport of sperm. If the proper hormonal events do not occur, fertilization and pregnancy become much less likely, especially in the presence of other causes of impaired fertility such as a low sperm count in the male (53). Less commonly, insufficient mucus production due to physical destruction of endocervical tissue during surgery is also associated with evidence of decreased sperm transport (112). Other possible causes of poor cervical mucus are secretory antibodies in the mucus, infection (cervicitis), and exposure to diethylstilbestrol (DES) (1). The effect of the change in the cervical mucus on fertility is highly controversial (71), and it is not considered a frequent factor leading to infertility.

Hyperprolactinemia: Physiologic and Pathogenic

In all mammals, including humans, lactation is a key link in the reproductive cycle (133). Ovulatory suppression prevails during nursing and serves as a primary means of birth spacing for humans (130,150). Continued suckling keeps levels of the hormone prolactin elevated to some degree (83), and elevated levels of prolactin suppress ovulation by affecting both hypothalamic-pituitary and ovarian processes (133). Lactation is not associated with any long-term fertility impairment.

However, hyperprolactinemia—the overproduction of the hormone prolactin—is identified as a factor contributing to infertility (115). It is associated with impaired fertility in the presence and absence of excessive milk production. Consistently hyperprolactinemic women are almost always infertile (115).

Hyperprolactinemia can also be associated with infertility in males, although it is rare in comparison with female cases. Hyperprolactinemia in men is associated with decreased levels of testosterone and markedly decreased spermatogenesis (13), but it is only significant when prolactin is markedly elevated and related to a tumor (100).

Causes of hyperprolactinemia are diverse and remain poorly understood. At least half the patients evaluated show evidence of pituitary tumor. Various medications, hypothyroidism, stress, exercise, excessive breast stimulation during lovemaking, and other causes of chest wall stimulation have been implicated in hyperprolactinemia.

Exercise

Considerable accumulated evidence indicates that regular, strenuous exercise alters menstrual function and temporarily impairs fertility in women. In males, gonadal steroid production may also be altered by rigorous training (104,186), but exercise does not appear to have an effect on male fertility. The frequency of amenorrhea (absence of menstruation) or oligomenorrhea (infrequent menstruation) among women participating in a variety of activities varies from 2 to 51 percent as opposed to 2 to 5 percent of more sedentary women (26). In a prospective study of women with previously normal menstrual cycles, fully 87 percent developed abnormality of these cycles when engaged in a strenuous exercise program (21).

Hormonal abnormalities described include disordered gonadotropin release and levels, decreased estrogen levels, corpus luteum inadequacies, and complete anovulation (48,131,137,145, 146). Abnormalities appear greatest when exercise is most intense or when training becomes more rigorous (103,131), although a recent study did not find training intensity of Olympic-caliber marathon runners to be a key factor in loss of menses (63). Researchers suggest that even moderate exercise by recreational women runners (average 12.5 miles per week) reduces overall progesterone levels but does not delay luteal progesterone rises, which are suggestive of ovulation (48).

Mechanisms of menstrual irregularities associated with strenuous exercise regimens are not completely understood. It has been suggested that exercise results in changes in prolactins and endorphins, possibly affecting fertility (47,103). At this time, little information exists on the relationship between exercise-associated menstrual alterations and long-term infertility.

Poor Nutrition

In women, it is generally accepted that sexual maturation and continuation of cyclic ovulation depends on achieving and maintaining an adequate amount of body fat as a proportion of total body mass (59,60,166). Fatty tissue appears to directly influence reproductive maturation and function in both sexes by metabolizing both androgens and estrogens that, in turn, influence the central nervous system, hypothalamus, pituitary, and reproductive tract organs in complex ways (59,166). Too little and (much less commonly) too much adipose tissue have each been associated with impaired fertility.

According to estimates of one researcher, completion of pregnancy and lactation requires approximately 50,000 calories—roughly the amount of energy most normal women (26 to 28 percent body fat) possess in body fat (59). Because fat is the most labile and sustainable source of body energy, possession of adequate fat stores may serve as a physiologic precondition for conception and pregnancy. Obesity is also associated with anovulation, endometrial hyperplasia, and subsequent hemorrhage (35).

Stress

Interactions with surroundings can cause bodily changes that impair fertility, yet the relationship between stress (stimuli or conditions that perturb homeostasis and require adaptation) and impaired fertility is extraordinarily difficult to prove in humans.

Input from the limbic system and other brain centers affects the hypothalamus, the pituitary gland, and the neurohormonal axis that orchestrates both the physical and behavioral aspects of reproduction. This complicated system provides ample opportunity for stress to interfere with the homeostasis of the individual. In recent decades, 40 to 50 percent of infertility was attributed to stress or emotional factors (143). Recent progress in neuroendocrinology and reproductive medicine has reduced this estimate to 5 percent or less (143). However, some would argue that a certain percentage of idiopathic infertility may be stress-related.

Critical reviews of the large volume of information regarding stress and fertility in different lifestyles are available (38,39,111,189,190). In humans, evidence suggests that mild to severe emotional stress alters sexual behavior, interferes with ovulation, depresses testosterone, and perhaps interferes with spermatogenesis (111,143). In women, anorexia nervosa can cause amenorrhea, apparently independently of weight loss (69). Anecdotal accounts indicate that anxiety can play a role in infertility; for example, 10 percent of patients become pregnant after having made an appointment for or having had their first professional visit for infertility (46).

Neurotransmitters play central roles in adapting to stress. Furthermore, neurotransmitter roles are not limited to effects on the central, peripheral, or autonomic nervous system functions, but are also directly involved in reproductive tract physiology (65). Understanding of increasingly unified and shared concepts of organ system physiology is growing rapidly. Yet, despite this information, great difficulties persist in accurately attributing individual cases of human infertility to stress, whether primarily physical or psychological.

ENDOMETRIOSIS

Endometriosis is characterized by the presence of cells of the uterine lining outside of the uterus. The ovaries, fallopian tubes, pelvic peritoneum, and visceral peritoneum are the most common locations of endometrial implants, but other sites, such as pleura, lung, and lymph nodes, have also been reported (54). Endometriosis afflicts approximately 7 to 17 percent (studies range from 4 to 50 percent) of menstruating women (120).

When symptomatic, the process is classically characterized by painful menstruation, painful ovulation, painful intercourse, and infertility. Expression of each symptom varies and correlates poorly with the physical extent of endometriosis. One estimate states that 30 to 40 percent of women with endometriosis are subfecund (93). Evidence of endometriosis is frequently found in women with otherwise unexplained impaired fertility. There is some indication that pregnancy might ameliorate the effects of endometriosis; however, this claim is controversial (23).

Suggestions on how endometriosis might impair fertility are multiple and not mutually exclusive; they include interference with ovulation, ovum transport, or implantation, or induction of early spontaneous abortion (66,81). Clinical and laboratory animal evidence supports each of these mechanisms. These processes may be mediated in turn by physical scarring; by increased destruction of male or female gametes; by growing numbers of activated peritoneal or tubal macrophages (cells that ingest other cells); by altered tubal, ovulatory, or corpus luteum function because of altered prostaglandin secretion; or by autoimmune phenomena (66,67). Overall, the precise mechanisms contributing to infertility in conjunction with endometriosis when organic and structural abnormalities are absent remain poorly understood.

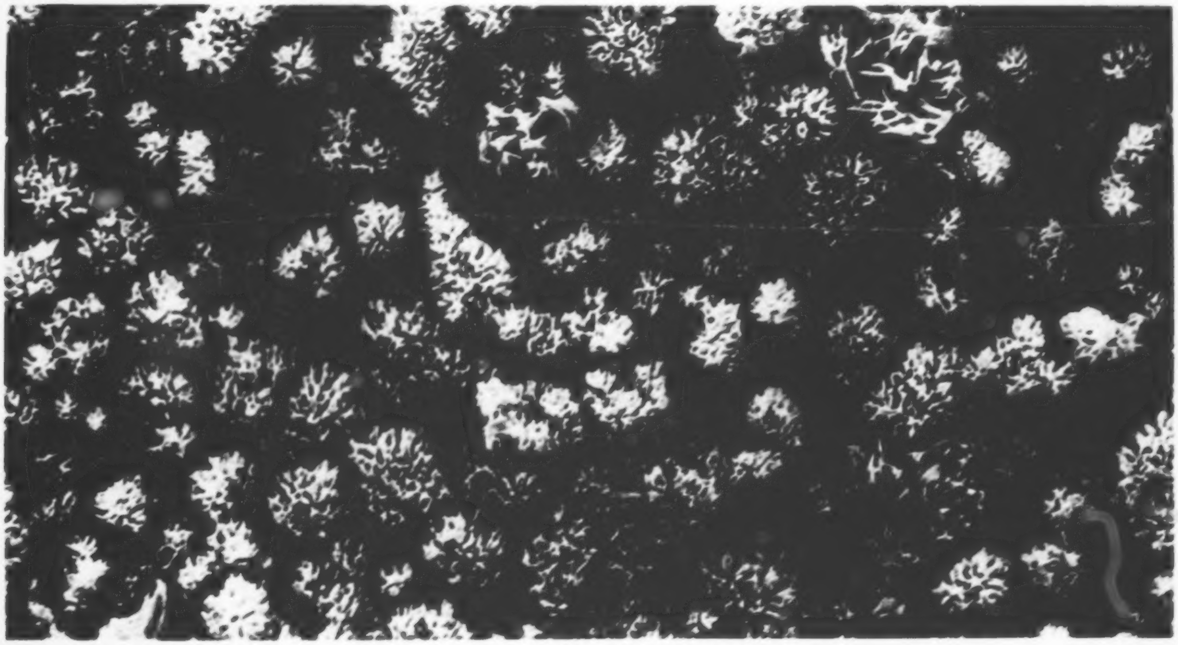


Photo credit: Walter H. Wilborn, Electron Microscopy Center, University of South Alabama

Normal endometrial cells lining the uterus (3,750× magnification).

The development of endometriosis is also not completely understood. With rare exception, it is only ovulating and menstruating women who develop the condition. Some women, however, may be at greater risk. Genetic predisposition for initiation and propagation of endometriosis has been documented (132,152).

In general, theories on the development of endometriosis suggest that viable endometrial cells or tissue are transported directly and grow in a different location, that endometrial tissue arises in situ from local tissues, or that a combination of these processes holds. The first explanation has the most support. Many observers have noted "bits" of endometriosis within pelvic or other lymphatic areas "downstream" from the uterus. Vascular spread, primarily to the lung, is also possible and could account for rare cases where endometriosis is noted in diverse locations of the body.

Pelvic endometriosis is common and has been linked to retrograde menstruation (menstrual flow backwards through the uterine tubes) (138). Past or anecdotal evidence has suggested that intra-abdominal spillage of menstrual fluid during menses occurs in roughly one-third of ovulating women. Blood has been detected in peritoneal fluid of 90 percent of 52 women with unobstructed fallopian tubes undergoing laparoscopy in the perimenstrual period (67). A larger study in which elective laparoscopic sterilization was performed during menstruation showed that retrograde menstruation occurs in up to 78 percent of ovulating women (57 of 75 women, ages 26 to 48) (101).

VARICOCELE

A controversial contributor to male infertility is the testicular varicocele, or varicose vein of the testis. A varicocele is an abnormal dilation and twisting of the veins carrying blood from the testes back to the heart. Varicoceles most often occur in the left testis, most likely due to a difference in anatomy between the veins leaving the two testes (16).

Exactly how varicoceles lead to infertility is unclear; some suggestions are based on the possibility that the pooled blood overheats the testes, either killing the sperm or speeding up the sperm production process too much.

There is considerable controversy over the contribution of varicoceles to infertility. The estimated incidence of clinically evident varicoceles in the general male population varies from 8 to 23 percent. A recent study reported that a majority of a group of fertile males had either palpable or subclinical varicoceles (97). Whatever the incidence or contributory role, many experts believe that varicocele correction leads to improved fertility (97).

EXTERNAL FACTORS

Contraception

Contraception—intentional, temporary infertility—is sometimes linked to unintentional, long-term infertility. Contraceptives are extensively used, especially by young individuals whose reproductive years generally lie ahead of them. For this reason, the association of contraceptive use and fertility has been explored in detail.

Overall, types of contraception used vary with age, marital status, reproductive history, and race (9). In 1982, surgical sterilization was the most widely used method of contraception (18 percent). Next in popularity were birth control pills (16 percent), condoms (7 percent), diaphragms (5 percent), and intrauterine devices (IUDs) (4 percent) (9). About 2 percent of women used some form of periodic abstinence. Withdrawal, douche, foam, and suppositories were used by similarly small percentages of women.

Sterilization

Surgical sterilization is the most common form of birth control used in older age groups (9). In 1982, approximately 39 percent of currently married couples of reproductive age had been surgically sterilized for contraceptive reasons (116). Some of these couples may desire a reversal of the procedure, with a smaller percent actually obtaining the reversal (20).

For reversal of contraceptive sterilization in women, several factors are important in determining whether fertility can be restored: the surgical method initially used, tubal site, length of tube remaining, and surgical skill in restoration (180). Factors that are most important in male sterilization reversal are time elapsed since sterilization, surgical technique originally used (180), age at reversal (135), and skill of the surgeon.

Oral Contraceptives

Two studies of women with and without children who discontinued oral contraceptives in order to become pregnant demonstrate similar findings from vastly different parts of the world (124,170). Both studies found a small but significant initial impairment of fertility in women who discontinued pill use compared with women who discontinued other contraceptive methods. The magnitude of this relative decrease diminished rapidly with time and was probably due to transient pill-associated amenorrhea and anovulation. Other data from smaller studies confirm these findings (57). These modest fertility differentials primarily concern older women or couples with previously impaired fertility (155).

Estimates of the incidence of postpill amenorrhea range from 0.2 to 2.7 percent. Disagreement persists as to whether this syndrome is specific to pill use, is coincidental, or is related to the use of birth control pills to suppress anovulatory menstrual bleeding originally. Postpill amenorrhea in which no concomitant factors (e.g., weight loss, prior oligomenorrhea, hyperprolactinemia, or polycystic ovarian disease) (70,73) are found diminishes with time and responds quickly to ovulation induction (84).

Progesterone-only "minipills," which act primarily by inducing local genital tract alterations rather than inhibiting ovulation, are even less likely to impair fertility than combination pills (98). Data from several small studies suggest there is little or no ovulatory suppression after discontinuing minipills (57).

There is some evidence that oral contraceptive use may actually protect against tubal infertility (117). However, a recent study indicated no change in a woman's risk of tubal infertility with past use of oral contraceptives overall (41). The same study indicated that the association between tubal infertility and oral contraceptive use may vary with the amount of estrogen and type of progestin in the oral contraceptive used, with users of estrogen-dominant pills slightly more at risk for tubal infertility. Finally, oral contraceptive use may provide some protection against uterine and ovarian cancer and may decrease the frequency of ectopic pregnancy (86).

Injectable Contraceptives

Much concern exists about the delay in the return of fertility following the use of various injectable hormonal contraceptives (56). However, no evidence suggests that injectables permanently impair fertility. On average, the delay in return to fertility following discontinuation of use results from the time required to clear the drug from the body (47). One such hormonal contraceptive, Depo Provera, results in a median delay in conception of 5.5 to 7 months after the term of complete contraceptive protection ends (56). This is 1 to 4 months longer than the median conception time following intrauterine device discontinuation (56,57,125). A number of other injectable contraceptive formulations are less well studied but none of them appear to decrease fertility after the medication is metabolized (56,57).

Intrauterine Devices

Based on recent, well-controlled studies, IUD use is thought to increase a woman's risk for tubal infertility (42,44). Women who did not have any prior births and who had ever used an IUD were about twice as likely to suffer from tubal infertility subsequently as women who had never used an IUD. However, the risk varied by type of IUD used, with the greatest risk being evident for the Dalkon shield and the lowest risk apparent for copper-containing devices. In one study (42), IUD users who reported having only one sexual partner were not found to be at increased risk.

Earlier studies that followed up large populations of women who stopped using an IUD and measured the length of time until conception found that cumulative conception rates for IUD users and nonusers were similar (161,169,172). In most of these studies, however, the women were married and had had a prior pregnancy. Also, many of the studies included only women who had used an IUD successfully; women who had experienced medical complications associated with IUD use were excluded from the analyses. Both these factors would have the effect of masking an increased risk for infertility (117).

Some IUDs have been associated with an increased risk for PID (92,184) and this is thought to be the reason for their association with tubal infertility. IUDs were largely withdrawn from the market in the 1980s because of their potential association with tubal infection. Only one, the Progestasert® system (ALZA Corp., Palo Alto, CA) is available in the United States. A copper-containing IUD developed by researchers at the Population Council and approved by the U.S. Food and Drug Administration in 1984 is slated for marketing by GynoPharma Inc. of Somerville, NJ, in 1988 (154). This IUD, the T-380A, has been used in other countries since 1982.

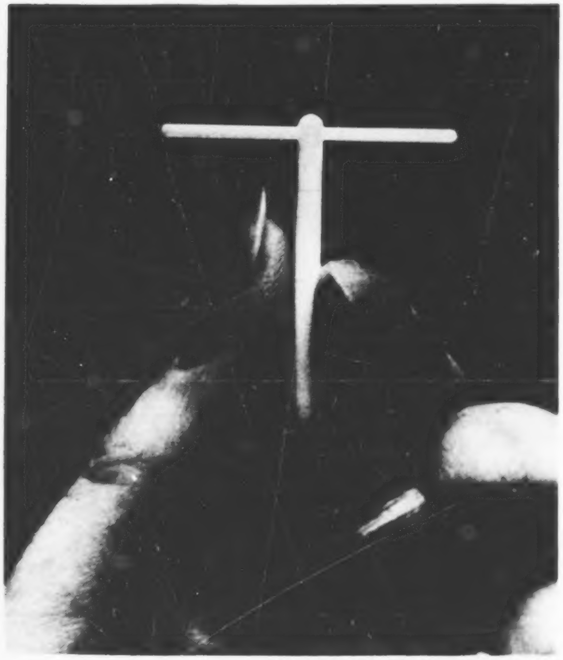


Photo credit: ALZA Corp., Palo Alto, CA

Progestasert® intrauterine progesterone contraceptive system.

Other Contraceptives

Use of most other effective forms of contraception is not linked to any specific fertility impairment beyond that associated with aging. However, a recent study found that a greater proportion of infertile women with abnormalities of the cervical mucus had previously used a diaphragm than had fertile women (43). Effects on subsequent fertility caused by use of newer agents, such as the progesterone antagonist RU486, remain unstudied (40). Barrier methods have been shown to offer protection against STDs (41).

Abortion

Approximately 90 million births occur worldwide each year (40) and some 33 million to 60 million abortions (both legal and illegal) (64). In the United States, approximately 3.7 million births and 1.6 million legal abortions are recorded annually (77).

The impact of induced abortion on subsequent fertility has been extensively reviewed (45,79,80). With the exception of an early study from Greece (162), where abortion is illegal and therefore is primarily carried out in unsanitary conditions, these studies indicate there is no increased risk for infertility following legal induced abortion. Indeed, two studies report significantly shortened interpregnancy intervals following abortion (78,158). These findings are most probably explained, however, by enhanced fertility in women with unplanned pregnancies rather than any enhanced fertility due to the abortion itself.

Environment and Drugs

Currently no reliable estimates can be made of reproductive risk from environmental factors. Until recently, little attention was paid to environmental and drug-induced infertility and subfecundity. However, four health hazards—ionizing radiation, lead, ethylene oxide, and dibromochloropropane—are regulated in part because of their effects on the reproductive system. Possible environmental hazards include chemical agents; physical agents such as altitude, temperature, and radiation; and personal habits such as smoking, alcohol consumption, use of drugs (both therapeutic and nontherapeutic), and eating patterns (164).

Industrial exposures that may interfere with fertility are presented in table 4-1. Because possibly toxic agents vary in importance and in how much is known about them, only a few substances are selectively discussed here. Many more agents are known to be associated with poor reproductive outcomes (e.g., teratogenicity, growth retardation) than with infertility (12), but this may be because the connection between toxic exposures and infertility has not been studied as carefully as other reproductive outcomes (117).

Glycol ethers, a chemical species found in a wide variety of products, including paints, stains, varnishes, and solvents, are the best studied of reproductive toxicants (72). This important and widely used class of solvents is embryotoxic and teratogenic (causing defects in formation) in male and female animals, and it produces testicular atrophy and infertility in male animals; studies have confirmed that glycol ethers can cause oligospermia, azoospermia, and decreased sperm count per ejaculate in human males as well (165,181).

In utero exposure to DES is associated with abnormal reproductive development in males and females when they mature. Development of vagi-

Table 4-1.—Industrial Exposures That May Affect Reproductive Health

Metals	Chemicals	Undefined industrial exposures
Antimony	Agricultural chemicals:	Agricultural work
Arsenic	Carbaryl	Laboratory work
Boron	Dibromochlorpropane (DBCP)	Oil, chemical, and atomic work
Cadmium	DDT	Pulp and paper work
Chromium compounds	Kepone (Chlordecone)	Textile work
Lead	2,4,5-T Dioxin (TCDD) and Agent Orange	
Manganese	2,4-D	
Mercury	Anesthetic agents	
	Epichlorohydrin	
	Ethylene dibromide (EDB)	
	Ethylene oxide (EtO)	
	Formaldehyde	
	Organic solvents:	
	Carbon disulfide	
	Dinitrotoluene and toluene diamine	
	Styrene	
	Benzene	
	Carbon tetrachloride	
	Trichlorethylene	
	Polyhalogenated biphenyls:	
	Polybrominated biphenyls (PBB)	
	Polychlorinated biphenyls (PCB)	
	Chemicals in rubber manufacturing:	
	1,3-Butadiene	
	Chloroprene	
	Ethylene thiourea	
	Vinyl chloride	
	Hormones	

SOURCE: U.S. Congress, Office of Technology Assessment, *Reproductive Health Hazards in the Workplace*, OTA-BA-266 (Washington, DC: U.S. Government Printing Office, 1985); D.D. Baird and A.J. Wilcox, "Effects of Occupational Exposures on the Fertility of Couples," *Occupational Medicine: State of the Art Reviews* 1:361-374, 1986.

nal cancer in daughters of DES users, although rare, is significantly more common than among nonexposed women, and exposed women are known to have a higher proportion of reproductive tract anomalies resulting in infertility (117). Reports suggest that males exposed to DES commonly have abnormal spermatozoa and potentially diminished fertility (156).

The effects of physical agents on fertility are outlined in table 4-2.

Certain medications and substances used for self-intoxication can also interfere with fertility. Most prominent among these agents are cigarette smoking (discussed in next section) and chronic and acute alcohol consumption. Chronic alcohol abuse is consistently associated with abnormalities of spermatogenesis and presumed subfecundity in males. Although alcohol consumption impairs fertility in laboratory animals through a variety of mechanisms, human infertility from "moderate" nonhabitual alcohol consumption is not apparent (123).

Table 4-2.—Summary of Effects of Physical Forces on Fertility

Condition	Comment
Atmospheric pressure	
Low (high altitude)	Lower human birth rate
High (scuba diving)	No data
Electric and magnetic fields (many sources)	Possible increase in congenital malformations
Gravity and acceleration	No adverse effects noted
Hyperthermia	Reversible damage to spermatogenesis
Hypothermia	No adverse effects noted
Ionizing radiation	Dose-dependent effects at high but nonlethal doses; reduce to "as low as reasonably achievable"
Noise	Conflicting results
Optical radiation (UV, visible, infrared, laser)	No adverse effect noted Subjective complaints with video displays
Radio-microwave radiation	No adverse effects in absence of measurable heating
Ultrasound	Not adequately studied
Vibration	Little data

SOURCE: American Medical Association Council on Scientific Affairs, "Effects of Physical Forces on the Reproductive Cycle," *Journal of the American Medical Association* 251:247-250, 1984; H.B. Holmes, *Risks of Infertility Diagnosis and Treatment*, prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, August 1987; S. Nordstrom, E. Birke, and L. Gustavsson, "Reproductive Hazards Among Workers at High Voltage Substations," *Bioelectromagnetics* 4:91-101, 1983.

Marijuana use has also been implicated in reproductive impairment, although studies present conflicting results. Decreased hormone levels in men and women, ovulatory disorders in women, and decreased sperm counts in men have been associated with infertility in some studies. The development of tolerance to the drug may account for some of the conflicting data (153).

Smoking

Experimental evidence in animals indicates that cigarette smoking has adverse effects on reproduction. In humans, evidence suggests that smoking has a deleterious effect on menstrual cyclicity, oocyte production, and tubal function (136).

Variously designed epidemiological studies from different countries confirm an association between smoking and infertility and menstrual abnormalities in women (11,74,123,160). Other studies have noted the adverse effects of smoking on tubal function (157). A recent study noted significant association between cigarette smoking and primary infertility resulting from cervical factors and tubal disease (128). No association between smoking and ovulatory factors was found in this study. Finally, smoking can shorten the reproductive lifespan by decreasing the age of menopause in a dose-related way (89).

In males, some studies have found that smoking or nicotine consumption is associated with decreased sperm motility and count, altered sperm morphology, and altered hormonal levels (179, 182). Experimental findings suggest that these alterations are caused by changes in hypothalamic pituitary axis function and possibly by impaired motility of cilia in the genital tract (110). One study found that smokers with testicular varicoceles had a tenfold increase in incidence of oligospermia over nonsmokers with varicoceles, and a fivefold increase in incidence of oligospermia over smokers without varicoceles (94). Other studies have found no significant effect of cigarette smoke on sperm density, motility, or morphology (171).

Congress has recognized the harmful effects of smoking on the reproductive system. In 1985, new warning statements were required (Public Law 98-474) on the packages and advertising of all cigarette brands sold in the United States (177). Two of these statements call specific attention to the reproductive hazards caused by smoking:

> **SURGEON GENERAL'S WARNING**: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.
> **SURGEON GENERAL'S WARNING**: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.

Spinal Cord Injury

The outlook for fertility in paraplegic men after spinal cord injury is poor; the outlook for paraplegic women is often better. Paralyzed men often (but not always) suffer from impotence because of neurological deficits in the spinal cord. Problems resulting from spinal cord injury include inability to achieve an adequate erection, inability to ejaculate normally, infection resulting from prolonged or intermittent catheterization, and decreased sperm quality. This topic is discussed in detail in chapter 10.

GENETIC AND CHROMOSOMAL ABNORMALITIES

Genetic and chromosomal abnormalities can affect fertility in several ways. Most significantly, abnormalities in human embryos can lead to early fetal loss, and genetic diseases (e.g., cystic fibrosis) that are not serious enough to cause embryonic death can impair reproductive function in adults. Many of the factors contributing to infertility mentioned elsewhere in this chapter may have genetic components.

Substantial pregnancy loss occurs between implantation and the time pregnancy is usually recognized (173), some portion of which may be caused by chromosomal abnormalities of early embryos. Abnormalities can affect the chromosomal health of a human embryo in five ways:

- The sperm can have a chromosomal abnormality. One study found that approximately 9 percent of human sperm are abnormal (107).
- The oocyte can be abnormal. A study of infertile women undergoing clomiphene stimulation found that nearly 50 percent of the oocytes recovered were abnormal (188). Chromosomal abnormalities of human oocytes are known to increase as a woman ages. (The women described in this study may be representative of all women of their age group (mean age 30.8), but they are probably not representative of women of all ages.)
- The early embryo can fail to divide (35).
- The early embryo can drop or fail to incorporate one or more chromosomes, resulting in an incomplete set of chromosomes (141).
- There can be double sperm penetration, leading to triploidy (141).

Chromosomal abnormalities of human embryos are thus a sum of these problems. Limited data suggest that from 23 to 50 percent of human embryos may have chromosomal abnormalities (4,129,167).

Chromosomal abnormalities that do not cause early fetal loss can also impair the reproductive functioning of an adult. The spectrum of chromosomal abnormalities associated with infertility is more complex than originally supposed (151). Mutations or deletions of sex-determining chromosomal regions have been linked with infertility (95). Women with XO, XY, and other abnormalities are subfecund or sterile. A region of the long arm of the X chromosome appears essential for normal ovarian function; deletion of this region is associated with premature ovarian failure (51,96). Furthermore, the genetic makeup of an individual may predispose that person toward certain diseases, such as cancer or endometriosis.

A number of Mendelian traits, most of which are extremely rare, are associated with infertility (151). In Caucasians, the most common of these is cystic fibrosis, with an incidence of 1 in 1,600 to 1 in 2,000 individuals (142). With contemporary multisystem supportive care, half of all cystic fibrosis patients survive to age 19. This trend is expected to continue, allowing many more patients to survive into reproductive age groups. Puberty is commonly delayed in cystic fibrosis patients and the degree of delay correlates primarily with severity of illness and height-weight ratios (142). In males with cystic fibrosis, abnormalities of the vas deferens are common (100). Although pulmonary disease of any origin can restrict sexual performance, most couples in which one partner has cystic fibrosis can have sexual relationships (99). In earlier decades, most affected individuals died before reaching reproductive potential.

CANCER

Cancer can affect fertility in three ways. As with many diseases, the very presence of cancer in the body is known to affect semen quality (122) and is likely to affect the female reproductive process as well. The tumor itself can affect fertility if there is direct gonadal involvement. Finally, treatment of cancer—surgery and therapy (radiation and chemotherapy)—can also reduce fertility (see table 4-3).

Obviously, fertility will be impaired if there is direct damage of female or male genital tract structures required for procreation. Cervical, uterine or endometrial, ovarian, and testicular neoplasia are not uncommon. (Neoplasia refers to the progressive multiplication of cells under conditions that cause the cessation of multiplication of normal cells.) Cancer of the cervix, of the uterus, and to a lesser extent ovarian cancer are associated with certain risk factors involving lifestyle, possible carcinogenic exposures, and inherited predispositions (14). Infertility caused by hormone deficiency can be a risk factor for uterine cancer (134). Cervical and, to a lesser extent, vaginal and vulvar cancer have been associated with increased numbers of sexual partners and the increased occurrence of sexually transmitted disease. Development of endometrial cancer is associated with a history of sustained high-fat diet and prolonged periods of anovulation or relative infertility. For testicular cancer, undescended testes, prior history of mumps orchitis, an inguinal hernia in childhood, and previous testicular cancer in the other testis have been identified as risk factors, but in the majority of cases no predisposing factors are evident (19).

Table 4-3.—Reproductive Consequences of Cancer and Cancer Therapy

Cancer or therapy	Consequences
Tumor	Direct gonadal involvement
Surgery	Removal of gonad
	Neurogenic dysfunction Failure of emission Retrograde ejaculation Loss of orgasm
Therapy	Germ cell depletion Clinical hypogonadism Mutagenic changes in germ cell Teratogenic effects on fetus Seminal transmission of drug

SOURCE: R.J. Sherins, "Reproductive Hazards of Radiotherapy and Chemotherapy in Adult Males," paper presented at the International Conference on Reproduction and Human Cancer, Bethesda, MD, May 12, 1987.

Therapeutic removal of genital tract structures will obviously lead to infertility if not sterility. Surgical procedures involving areas such as the prostate may also result in infertility; prostate surgery often leads to impotence in males. Modification of surgical procedures has drastically reduced the problems associated with male cancer surgery (147), but a recent study found a 20-percent fertility deficit in men treated with surgery for childhood cancer. Women treated with surgery in childhood or adolescence had almost no fertility deficit (24).

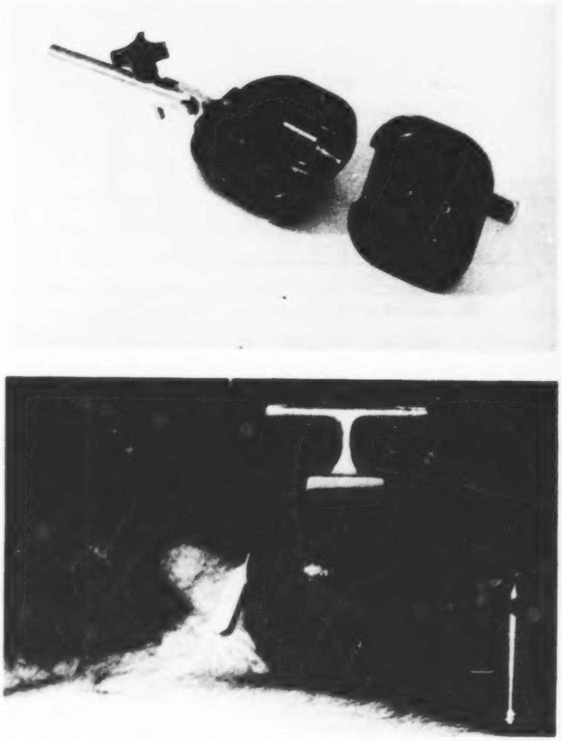
Transient or permanent gonadal damage and dysfunction may also occur during cancer therapy with radiation and chemotherapy. The National Cancer Institute has developed a device to prevent testicular damage in male patients undergoing radiation therapy (see figure 4-1). Research suggests that the impacts of various treatments vary by age, sex, type of cancer, type of drug, total drug or radiation dose, duration of treatment, use of single v. multiple agents or combined modalities, and length of time since cessation of treatment (91,144,148).

Germ cells have a normal mutation rate of approximately 12.5 percent (50). Cancer therapy causes an increase in the mutation rate, which decreases quickly with cessation of treatment but remains higher than normal for about 10 years. In men, nearly all cytotoxic agents used in cancer therapy produce at least a temporary reduction in sperm counts. However, even after 2 to 3 years of total azoospermia, sperm production can gradually return to normal levels (114). One study reports that for all forms of therapy combined, the fertility of male cancer survivors is decreased significantly while the fertility of female cancer survivors is not. Radiation therapy is the exception; it affected men and women similarly (24). Newer regimens for treatment of testicular cancer affect spermatogenesis less than earlier ones, since they use less toxic drugs and do not last as long (18).

Various effects of cytotoxic drugs and radiation on the ovary have been described. These include ovarian fibrosis, follicular destruction, reduced estradiol levels (estradiol is a form of estrogen), increased follicle-stimulating and luteinizing hormone levels, amenorrhea, and premature menopause (probably the most frequent effect) (10). Ovarian failure in these circumstances is age-related, with older women being predisposed to sterility at lower dose regimens (144).

Overall, Hodgkin's disease and male genital cancer appear to cause the greatest decrease in fertility (24,112). Precise information on thresholds of gonadal vulnerability and ability to recover depends on the drug, dosage, or amount of radiation used. The influence of pubertal status remains controversial (91,144).

Figure 4-1.—Testicular Shield



The National Cancer Institute has developed a shield designed to protect the testes from scatter radiation during cancer therapy. The shield is recommended for patients receiving radiation treatment to the lower abdomen, pelvis, and thigh. It is constructed of lead and coated with plastic.

SOURCE: T.J. Kinsella, Deputy Chief, Radiation Oncology Branch, Clinical Oncology Program, Division of Cancer Treatment, National Cancer Institute, personal communication, June 25, 1987.

IATROGENIC FACTORS

Iatrogenic factors contributing to infertility are those produced inadvertently by physicians or by treatment by them. Procedures listed in table 4-4 can lead to infertility, especially when not performed properly. The most common of these is tubal occlusion resulting from contraceptive sterilization. Obviously the intent of tubal sterilization is tubal occlusion, but for the small percentage of women who want the sterilization reversed, a poorly done procedure can mean later undesired infertility.

Surgical procedures can impair a woman's fertility primarily by producing fallopian tube or ovarian adhesions (as well as by causing infection, as discussed previously). Much information links appendicitis, appendectomy, overuse of dilation and curettage (the procedure used to remove remaining placental material after pregnancy or spontaneous abortion), and other pelvic operations with tubal-based infertility (35,118,163).

Table 4-4.—Iatrogenic Causes of Infertility

Procedure	Finding
Tubal sterilization	Tubal occlusion
Vasectomy	Blockage of vas deferens
Misdiagnosed incomplete abortion	Tubal occlusion or adhesions
Ovarian wedge resection	Tubo-ovarian adhesions
Ovarian cystectomy	Tubo-ovarian adhesions
IUD insertion or retained IUD	Tubal occlusion or adhesions
Appendectomy	Tubo-ovarian adhesions
Uterine suspension	Partial tubal obstruction
Cesarean section	Tubo-ovarian adhesions
Hysterosalpingogram	Tubal occlusion
In utero exposure to DES	Hypoplastic uterus Poor cervical mucus Increased susceptibility to adhesions following trauma such as D&C
Infant hernia repair	Blockage of vas deferens
Dilation and curettage	Scarring and Asherman's syndrome

SOURCE: Adapted from W.R. Keye, "Avoiding Iatrogenic Infertility," *Contemporary Obstetrics/Gynecology* 19:185, 1982.

MISCELLANEOUS FACTORS

Sexual dysfunction may contribute to infertility in as many as 5 percent of infertile couples (139). In the male, these conditions usually fall into one of three categories; impotence, which can have psychological or organic causes; premature ejaculation, which, if severe, causes failure of sperm transmission to the female reproductive tract; and retrograde ejaculation, where semen is propelled into the bladder rather than out through the penis. Sexual dysfunction in the female can also affect reproduction, although negative consequences of these disorders on fertility are not as common.

It is possible that immunological factors may be associated with otherwise unexplained infertility (106,109). Three such potential factors are antibodies to sperm (from the male or the female), cellular immunity to sperm, and antibodies to the oocyte zona pellucida (105). A number of studies in humans have demonstrated impairment of fertility with sperm antibodies. Since normally fertile men and women frequently possess such antibodies, it has been suggested that they play a role in destroying aging sperm (41). Development of such antibodies is not understood. It is presumed that women develop antibodies to sperm or seminal plasma antigens during intercourse. Details of the specific stimuli and time course in developing such antibodies remain unstudied. The roles of cellular immunity and antibodies to the zona pellucida in infertility are not as well established. Despite enthusiasm for greater recognition of immunologic infertility, controversy surrounding the subject makes it an unsettled area (55,108).

Macrophages can occur in elevated numbers during menstruation, possibly due to the release of chemotactic or irritating substances from retrograde menstruation or infection (68). Macrophages are thought to destroy male and female gametes and play roles in adhesion formation (112).

Inflammatory bowel disease—ulcerative colitis (recurrent ulceration of the colon) and Crohn's disease (regional inflammation of the ileum)—occur most frequently in reproductive-age individuals, with approximately equal frequency between the sexes (62,88,168). Ulcerative colitis does not appear to impair fertility (168). On the other hand, a preponderance of reports suggest that Crohn's disease is associated with diminished fertility; mechanisms are not well established.

Another miscellaneous cause of subfecundity is cervical incompetency (52). If the cervix is not strong enough to support the added weight as a pregnancy progresses, it will dilate prematurely and spontaneous abortion can occur.

Premature menopause, defined as the cessation of menses prior to age 40, has been estimated to occur in 1 to 3 percent of American women. Furthermore, estimates state that approximately 10 percent of women with amenorrhea have premature menopause, meaning that in total at least 130,000 women in the United States suffer from this problem (6).

UNEXPLAINED INFERTILITY

In approximately 3 to 20 percent of infertile couples, no clinically apparent cause of infertility is demonstrable using standard techniques (34,127, 159). Although couples cannot be placed in this category until a thorough investigation has been performed by an infertility specialist, couples with unexplained infertility may actually suffer from subclinical expression of acknowledged causes of infertility that could be revealed by further testing or continued observations. Laparoscopy performed on 50 women whose couple evaluations were normal revealed that 28 (56 percent) demonstrated either previously unsuspected peritubal adhesions or endometriosis (187). Of those who had abnormal findings, 16 received appropriate treatment and 50 percent became pregnant within a year of treatment, versus 10 percent in the women who had no abnormalities (187). Other candidates for causes of unexplained infertility include numerous immunological abnormalities (127), luteal phase cysts, poor progesterone surge, abnormal sperm-mucus penetration, abnormal sperm-egg penetration (75), and factors known to prevent the sperm from penetrating the egg (58) (as demonstrated by a sperm penetration test).

Reports disagree on the prognosis for couples with unexplained infertility. Some claim these couples have a higher probability of conceiving than the general infertile population (15); others claim lower (90).

SUMMARY AND CONCLUSIONS

The factors contributing to infertility are often multiple and the boundaries between them are not clear. Accepting this limitation, certain general statements can be made.

In women, the main contributors to infertility are hormonal disturbances, blocked or scarred fallopian tubes, and endometriosis. Hormonal disturbances can arise from a number of different sources, and they can result in abnormal or nonexistent ovulation. Blocked fallopian tubes result most often from infection by pelvic inflammatory disease (often caused by sexually transmitted diseases) and inhibit or prevent transport of the egg and sperm. Endometriosis is characterized by the presence of cells of the uterine lining outside of the uterus and may interfere with nearly every phase of the reproductive cycle.

In men, most cases of infertility result from abnormal or too few sperm, although sometimes the transmission of sperm is a problem. A number of factors, including testicular varicoceles, environmental hazards, drug abuse, and cancer, have been implicated in male infertility, although much less is known about factors leading to male infertility than about those leading to female infertility.

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Prevention of Infertility

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Chapter 5

Prevention of Infertility

More is known about treating infertility (see ch. 7) than preventing it. Nevertheless, prevention strategies are desirable because they can avert the emotional and economic costs associated with infertility treatment, as well as preempt some infertility that would be wholly untreatable.

The most preventable type of infertility is that caused by sexually transmitted diseases (STDs). An estimated 20 percent of infertility in the United States results from STDs (4), while in some regions of the developing world the figure is up to 80 percent (25). It is noteworthy that changes in sexual behavior, attitudes about discussion of sex, and health education wrought by the epidemic of acquired immunodeficiency syndrome (AIDS) could have the salutary effect of preventing some infertility due to STDs. But the majority of cases of infertility are not due to these diseases but instead to factors that are difficult, if not impossible, to prevent (see ch. 4).

PREVENTION STRATEGIES

Primary prevention strategies are those aimed at avoiding a disease process entirely. This can be accomplished by health promotion activities, specific medical methods of protection, or diagnosis and treatment of infection or other ills among transmitters. Secondary prevention aims at reducing morbidity once an infection or a disease has already been acquired, and restricting its spread through the population. Infertility—a clinical condition often treated by medical or surgical means, and in some instances secondary to an underlying disease—is notably difficult to prevent, although it is the target of prevention strategies at both levels.

Primary Prevention

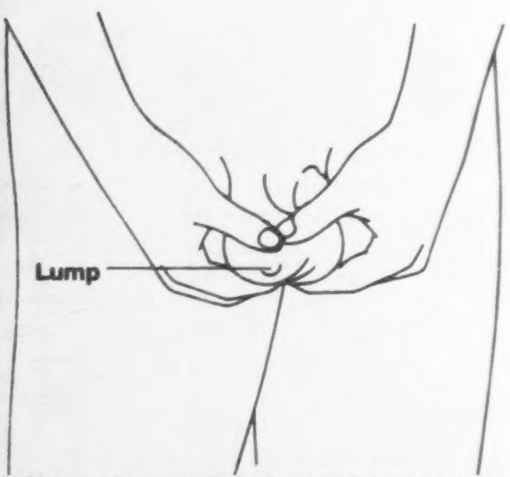
Little solid evidence can be cited of any useful means of primary prevention of male infertility. This follows logically from the finding that a principal factor leading to infertility in men is idiopathic oligospermia—i.e., sperm count reduction of unknown origin (see ch. 4). With the cause usually not known, primary prevention of infertility in the male becomes little more than guesswork (23).

On the other hand, enhanced awareness of the male reproductive organs is easily achieved among men and may occasionally lead to early detection of threats to fertility. Self-examination of the testes, and of the male genitalia in general, is a technique that deserves far more attention than it has traditionally received (see figure 5-1). Testicular self-examination is useful for detecting physical abnormalities and diseases, such as cancer of the testis, epididymal cysts, and STDs. Testicular cancer, which almost always occurs in only one testis, is highly curable when treated promptly. If a testicular tumor has begun to metastasize, surgical removal of the testis is usually accompanied by a dissection of the local lymph nodes to assess the extent of tumor spread. A major complication of such surgery is absence of ejaculation because of damage or removal of nerve fibers that run interspersed with the lymph channels (15,22).

Among women, the three main factors leading to infertility are tubal obstruction, endometriosis, and disorders of ovulation (see ch. 4). The principal means of avoiding tubal obstruction is primary prevention of STDs (discussed later in this chapter). Endometriosis can often be kept in check by oral contraceptives or drug therapy, but specific prevention strategies for this disease are unknown. Disorders of ovulation are probably the easiest to treat but they, too, are not clearly amenable to primary prevention (23).

With tubal ligation now the main means of contraception among women in the United States, and with vasectomy popular among men, obviously sterilization procedures must be undertaken carefully in order to prevent infertility that is later

Figure 5-1.—Testicular Self-Examination



Men can increase their chances of finding a tumor promptly by routinely performing a simple procedure called testicular self-examination.

Testicular self-examination should be performed once a month after a warm bath or shower. The heat causes the scrotal skin to relax, making it easier to find anything unusual. The procedure itself is simple and takes only a few minutes:

- **Stand naked in front of a mirror. Look for any swelling on the skin of the scrotum.**
- **Examine each testis gently with both hands. The index and middle fingers should be placed underneath the testis while the thumbs are placed on the top. Roll the testis gently between the thumbs and fingers. One testis may be larger than the other.**
- **Find the epididymis (a cord-like structure on the top and back of the testis that stores and transports the sperm). Do not confuse the epididymis with an abnormal lump.**
- **Feel for a small lump—about the size of a pea—on the front or the side of the testis. If you find a lump, contact a doctor right away. The lump may be due to an infection or it may be cancer. Many, if not most, cases of testicular cancer are curable. A doctor can determine the proper treatment.**

SOURCE: Adapted from U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, *Testicular Self-Examination*, NIH Pub. No. 85-2636 (Bethesda, MD: 1985).

unwanted. A host of other factors are weakly linked with infertility (see ch. 4). Table 5-1 reviews a range of primary and secondary preventive methods that might derive from these various contributing factors.

Table 5-1.—Prevention of Infertility

Factors predisposing individuals toward infertility and preventive steps available

Sexually transmitted diseases (STDs) and pelvic inflammatory disease (PID):
- Careful selection of possible sexual partners. Health education to discourage unprotected sexual encounters. Monogamy. Forthright inquiry and check of sexual partners for risks of STDs.
- Contraception by means of condoms. Use condoms routinely with new sex partner. Media campaign to encourage condom use.
- Periodic screening for STDs, if sexually active; STDs in both males and females are commonly asymptomatic.
- Changes in societal attitudes about STDs to lessen stigma of diagnostic examination for them.
- Recognize findings of STDs and seek medical care. Ensure that correct treatment is given for yourself and partner, with followup.
- Media campaign to encourage men and women with genital discharge to be checked for STDs.
- Rapid, adequate management of PID to reduce risk of sequelae.

Pelvic infections after birth, abortion, surgery, or invasive diagnostic testing:
- Ensure that optimally safe birth and surgical services are available.
- Use prophylactic antibiotics in high-risk situations to prevent infection.

Exercise, poor nutrition, and stress:
- Recognize that regular strenuous exercise (i.e., exceeding 60 minutes daily), rapid weight loss, low body fat, and stress may cause decreased fertility. Women are at higher risk than men.

Smoking, environmental toxins, and drugs:
- Smoking, as well as other substance abuse, reduces reproductive potential and should be avoided. Environmental exposures are inadequately studied, but appear more common in males. Semen analysis can be performed.

Endometriosis:
- If strong family history for endometriosis exists, consider oral contraception and possible specific endometriosis suppression. Oral contraceptives may suppress endometriosis even in those not at high risk.
- Early diagnosis and treatment in symptomatic women. Conservative surgical approaches.

Cryptorchidism and varicocele:
- Undescended, especially intra-abdominal, testes should be treated as promptly as possible. Benefits of surveillance and treatment of varicocele are controversial.

Chemotherapy and radiation:
- Risks of gonadal damage must be considered and, if appropriate, gamete collection or protection of the gonads should be performed.

Intercurrent illnesses:
- Many acute and chronic diseases cause anovulation or decreased spermatogenesis. Prevention of these effects is by treatment of the primary disease.

Inadequate knowledge of reproduction:
- Ensure that information on reproduction is available from parents, schools, clergy, and other sources.

Inadequate medical treatment:
- Couples with difficulty conceiving should educate themselves about fertility and seek specialized care before infertility is prolonged.

Lack of perspective about reproduction:
- Discuss family life with parents, peers, and professionals. Formulate life plan that allows adequate time for reproductive goals.

SOURCE: Office of Technology Assessment, 1988.

Freezing sperm for use at a later date can be thought of as a means of primary prevention of infertility that is subsequently caused by events either expected (e.g., radiation therapy for cancer) or unanticipated. In fact, as reproductive technology crosses new frontiers (see ch. 15), primary prevention of infertility may acquire an even fuller meaning. Cryopreservation of embryos—or ultimately oocytes—may give young women or young couples some assurance of avoiding infertility by being able to conceive months or years in the future despite intervening events that compromise their fertility.

Secondary Prevention

Once a symptom that foreshadows infertility occurs, a few steps can be taken to attempt to preserve fertility. As with primary prevention, secondary prevention focuses largely on STDs. Examples of such approaches include prompt recognition of signs of urethritis, vaginal infection, pelvic inflammatory disease (PID), epididymitis, or orchitis, followed by prompt evaluation by a caregiver, diagnosis, and effective treatment. Locating cases of STDs and sexual contacts of infected individuals is also an important means of secondary prevention since it allows for early diagnosis and treatment of individuals infected but not yet irretrievably affected by chlamydia or gonorrhea. In the case of endometriosis, it should be treated at the earliest possible opportunity—either medically or surgically—to provide the greatest likelihood of averting subsequent infertility.

SEXUALLY TRANSMITTED DISEASES

Infertility due to infectious disease—found in an estimated 20 percent of infertile couples in the United States—is distinguished by its preventability. Sexually transmitted diseases, principally gonorrhea and chlamydia, are important factors leading to infertility (see ch. 4). The specific risk is tubal occlusion secondary to the infection (25). The risk increases with the number of infections, the duration and severity of each infection, and any delay in instituting treatment; each of these components is a target for preventive efforts. (For a detailed review of the prevention of STDs, see 19,20.)

Public health initiatives aimed at preventing STDs and infertility include efforts in the following areas (3,6):

- health education of patients and public health professionals;
- disease definition, including long-term sequelae of STDs;
- optimal treatment and improved clinical service;
- partner tracing and patient counseling; and
- research, including on the social, psychologic, and biologic aspects of STDs.

In addition, research increasingly focuses on behavioral aspects of STD acquisition and prevention. Principles of primary prevention for sexually active individuals include: reducing the number of sexual partners; avoiding persons known to have many sexual partners; using mechanical barriers (i.e., condom, diaphragm, or contraceptive sponge) or chemical barriers (i.e., sper-

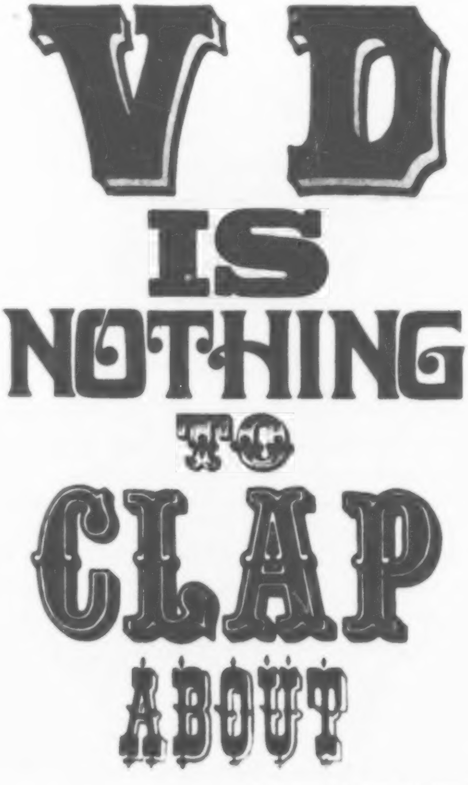


Photo credit: Library of Congress

Slogan promoting prevention of venereal disease micide); periodic screening for STDs; and prompt medical care if symptoms develop (2,5,7,16,19).

According to the Centers for Disease Control (CDC), STD control for the balance of the 1980s and into the next decade will focus on the primary prevention of all sexually transmitted infections, especially the persistent viral infections for which no therapies or vaccines exist (14). This emphasis is a new one, as historically the focus has been on secondary prevention efforts. If current primary prevention efforts are successful, an overall reduction in STDs will result. This would not affect those already afflicted with one of these diseases and associated infertility, but it may mean that infertility caused by STDs may ultimately decline.

A crucial step was taken in 1987 toward a vaccine against chlamydia, as researchers identified previously unknown details about the bacteria's outer coat. These findings should permit the synthesis of large quantities of the outer coat protein, a necessary step in developing a vaccine against chlamydia (18).

MATERNAL AGE

The calculus of infertility includes the age of the prospective mother. Female fertility decreases somewhat before age 35 and significantly more after age 35; in contrast, a decline in male fertility has not been linked to increasing age (see ch. 3). To avoid the decline in fertility related to age, some suggest that women should devote the third decade of life to childbearing and the fourth to career development rather than the other way around, as they are increasingly doing (8). Couples with access to child care or parental leave from employment may not be faced with so stark a choice.

Although no such social prescription fits all couples in all circumstances seeking to conceive, the biology of female fertility dictates that a couple maximize the number of months or years devoted to attempts at conception. Stated simply: The more months, the better; and the earlier the attempts, the better. A woman's reproductive lifespan is circumscribed, and whenever the decision to procreate is taken, the chances of success generally depend on the number of months during which conception is attempted. For some individuals, the equation is complicated by balancing the biological advantages of attempting conception early in their reproductive careers against the social disadvantages of entering the employment career market later in life.

IATROGENIC INFERTILITY

Surgical procedures can inadvertently impair a woman's fertility primarily by producing fallopian tube or ovarian adhesions (see ch. 4). Education and sensitization of practicing physicians about the risks to future fertility posed by abdominal surgery are the primary means of preventing iatrogenic infertility. Such education can stress, for example, the aggressive initial treatment of young patients with pelvic inflammatory disease, the conservative treatment that avoids pelvic surgery in young women, and the conservative surgical treatment of ovarian cysts (21).

The most common form of iatrogenic infertility occurs when a woman undergoes a tubal ligation and then seeks reversal. If the ligation was not carefully done in a fashion that conserved the fallopian tubes (e.g., if it was done with large and destructive cauterizing burns on each tube), the physician attempting to reverse the procedure is unlikely to be successful (23). One method of tubal ligation makes use of clips on the severed ends of the tubes—obviating the need for cautery—and offers the best probability for reversal.

Among men, iatrogenic infertility can also occur when sterilization—vasectomy—is done in too aggressive a fashion. Removal of too much of the vas deferens, for example, makes microsurgical reattachment exceedingly difficult. Another, hidden cause of male infertility stems from surgical repair of a hernia during infancy. Surgical closure of the hernia can inadvertently include the vas deferens, permanently blocking sperm transport from one or both testes.

Additional prevention strategies aimed at physicians include avoiding overprescription or incorrect prescription of fertility drugs that cause hyperstimulation and bursting of the ovaries, and avoiding repeated microsurgery that leads to excessive scarring of the fallopian tubes (9). Also, hysterectomy ought not be automatically accompanied by ovariectomy, as is sometimes the practice, when the option of egg retrieval for surrogate gestation is available. Finally, new medicines and surgical interventions must be evaluated for side effects on both female and male fertility.

EDUCATION

Effective advocacy of preventing infertility involves developing sophisticated and focused health education techniques appropriate for a pluralistic society. The twin targets of such educational efforts are medical care providers and individuals contemplating sexual activity. The imperatives of AIDS education and behavior modification will likely push frontiers of health-related education far further and faster than previously anticipated.

Medical care providers need specific undergraduate medical and postgraduate training to improve recognition and therapy of diseases that threaten fertility. Greater general recognition, for example, that *Chlamydia trachomatis* causes severe reproductive tract damage is an immediate goal that, if accomplished, would lead to earlier detection and treatment of these infections in men and women.

One of the national health objectives of the U.S. Public Health Service (PHS) states that by 1990, at least 95 percent of U.S. health care providers seeing patients with suspected cases of STDs should be capable of diagnosing and treating all currently recognized STDs (24). A 1986 review of progress toward this goal found that training for health care professionals in the treatment of STDs had improved in recent years, but still falls short of the necessary quality and scope (14).

Since 1979, PHS has emphasized four approaches to improving the training of clinicians treating STD patients. First, 10 STD Prevention/Training Centers were established to improve the diagnostic, therapeutic, and patient management skills of midcareer clinicians directly involved with STD patients. Second, PHS has funded the development and pilot testing of STD curricula in six medical schools. A 1986 survey found that STD training had increased in these schools to an average of 10 hours per student. The same survey showed that 44 percent of medical schools had no clinical curriculum on STDs. Third, PHS has funded an increasing number of STD Research Training Centers to encourage young scientists to pursue an academic career in STD research. Fourth, PHS has funded the development of an instructional package for clinicians who do not frequently see STD patients in their practices. Despite these efforts, the achievement of the 1990 PHS objective is in doubt (14).

A second PHS objective states that by 1990 every junior and senior high school student in the United States should be receiving accurate, timely education about sexually transmitted diseases (24). No systematic measures of this objective are available. In 1983, a Gallup poll found that only one-third of high school respondents considered themselves "very informed" and almost half considered themselves "somewhat informed" about STDs. The Centers for Disease Control has since placed increased emphasis on behavioral knowledge and attitudes related to biological facts. CDC actively promotes adoption of STD education for junior high and high school students, principally through State STD units. Increased attention to school-based education as a way to prevent AIDS should improve knowledge, attitudes, and behaviors affecting other STDs as well (14).

It is important to note that the influence that information and education can have on sexual behavior is limited (1). Individuals at greatest risk, for example, for PID may be resistant to conventionally given cautions. In one study, women with PID were more likely to take health risks, believe in luck, be more socially alienated, endure symptoms longer, and have coitus with a greater number of partners (12).

RESEARCH NEEDS

Developing and implementing effective and safe preventive strategies depends on thorough understanding of the problem. At present, vast gaps in knowledge impede further progress in preventing infertility. Immediate needs for research and further understanding include (11):

- **Fuller realization and broadened inquiries into all aspects of reproduction, including sexuality.** Reluctance to scrutinize such basic human characteristics and behaviors as these retards and distorts the ability to deal with the realities of reproduction as individuals and as a society.
- **More complete epidemiological definition and analysis of decreased fertility.** Present knowledge derives from relatively small, geographically and ethnically limited surveys and case reviews. Development of methodologic techniques and uniform terminology will be crucial for measuring all aspects of infertility and communicating the results.
- **Fuller understanding of social and economic aspects of infertility for young adults, women, men, families, and society at large.** Integration of careers and reproduction remains poorly studied in U.S. populations.
- **Inquiries into both normal and abnormal male and female reproductive physiology.** Rudimentary questions remain unanswered: How does aging reduce fertility? How do body mass and composition, as well as exercise and stress, influence reproductive ability? Solutions to these and other questions could offer means to prevent these causes of infertility.
- **Specific disease-oriented basic and clinical research, which can lead to dramatic advances in prevention.** Development of vaccines against various infectious diseases has been crucial to their control. Yet vaccine development for STDs, including *Neisseria gonorrhoeae* and *C. trachomatis*, is difficult because of incomplete understanding of the molecular biology and virulence of each organism and the means to induce a protective response in human hosts. With time and sustained supported effort, these difficulties can likely be overcome. In the meantime, new approaches to STD avoidance, detection, and treatment can be evaluated. Male responses to genital tract infections, for example, remain virtually unstudied with modern methods. Similarly, little is known about the pathogenesis or prevention of endometriosis. This common disorder remains a disease of hypotheses.
- **Better understanding of how to communicate most effectively health-related information to general populations and selected groups.** Such information has generally trickled down as news from various media or is dispensed piecemeal by care providers, parents, and friends. Initial attempts at using dynamic mass communication techniques for STD education are promising (10). The exigencies of dealing with AIDS will greatly expand and refine effective use of mass communication for motivating health-related behavior.
- **Development of reversible methods of sterilization and long-term contraception.** Contraception and conception—two sides of the same coin—are inextricably linked. Long-term contraceptives that are reliable and safe and do not place future fertility at risk are an important goal of research into preventing infertility.

A STRATEGY FOR PREVENTION

Any strategy for preventing infertility must possess certain characteristics to be effective. Such a plan must:

- be simple and understandable so it could be disseminated to the general population;
- be cost-effective—i.e., it should save more resources than it expends;
- respect individual privacy and not disrupt individuals' lives or their relationships; and
- offer an opportunity to measure its effect, so that results can be assessed.

In 1987, OTA convened a meeting of experts in Seattle, WA, to design a plan for preventing infertility that meets these four criteria (17,23). The strategy is based on people of reproductive age testing themselves to ascertain whether they have developed or acquired any risk factors for infertility. This type of preconceptional health questionnaire was recently used with a favorable response by women attending family planning clinics in North Carolina (13). Its primary purpose is not to identify people who are already infertile; rather, it seeks to identify men and women who may have a condition or lifestyle that could render them infertile in the future.

People in at least seven settings might be predisposed to completing a self-administered questionnaire concerning their reproductive potential. Each setting is one where relatively young people interact with the health care system. They are:

- individuals entering military service,
- women seeing their obstetrican/gynecologists for annual examinations,
- individuals attending family planning clinics,
- college students consulting the student health service,
- patients being seen in oncology clinics at risk of loss of their fertility,
- individuals having annual physical examinations, and
- individuals attending STD clinics.

A self-administered questionnaire can obtain information about an individual's nutritional status and social, family, medical, drug, and reproductive histories, while providing useful information keyed to the respondent's answers. Examples of specific questions and the related information that could be provided to the respondent appear in appendix B.

Implementation of this strategy for prevention has the potential to educate people exposed to the questionnaire, identify persons currently at risk who have not yet become infertile, identify persons who are already infertile, identify nonreproductive disease processes, and reduce iatrogenic infertility by enhancing patient awareness. On the other hand, such a questionnaire carries potential problems, including risking inappropriate responses by health care providers and causing respondents alarm, anxiety, guilt, regret, or apathy as their reproductive potential is described.

SUMMARY AND CONCLUSIONS

With the personal, familial, and societal losses caused by infertility inestimable and the economic costs so great, it is clear that infertility is better prevented than treated. Yet the former is more difficult. Only an estimated 20 percent of infertility—that caused by sexually transmitted diseases —is clearly amenable to prevention strategies. In those instances, curative medicine equals prevention of sexually transmitted diseases. Otherwise, the majority of cases of infertility are difficult, if not impossible, to prevent.

Prevention of male infertility is an enigma and will likely remain so as long as most male infertility is caused by reduced sperm count of unknown origin and little research addresses this question. Among women, tubal obstruction, endometriosis, and disorders of ovulation are the principal factors leading to infertility. Some tubal obstruction is preventable by avoiding sexually transmitted diseases, but specific prevention strategies for endometriosis and anovulation are largely unknown.

The biology of female fertility makes maternal age, especially beyond age 35, a factor in infertility. Although no social prescription fits all couples seeking to conceive, couples enhance their chances of success by maximizing the number of months or years devoted to attempts at conception, and doing so before maternal age becomes a significant factor.

Education of individuals contemplating sexual activity and of medical care providers about reproductive health and sexually transmitted diseases plays an important role in reducing threats to fertility. Gaps in their knowledge and even broader gaps in scientific understanding of normal and abnormal male and female reproductive physiology impede further progress in preventing infertility.

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Chapter 6

Diagnosis of Infertility

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Chapter 6

Diagnosis of Infertility

Determining that there is a need for infertility treatment is often a difficult and somewhat arbitrary decision. Some professionals suggest that after 6 months of carefully timed unprotected intercourse or, more commonly, after a year of random attempts at conception, a couple seek some form of infertility evaluation (8,33).

Although a growing number of physicians are specially trained in infertility treatment, most such treatment is still carried out by the female partner's gynecologist (1). Since most women visit a gynecologist more frequently than their male partners seek medical treatment, the gynecologist usually serves as the first professional an infertile couple encounters in their attempt to conceive. As much as 80 percent of basic infertility treatment occurs with the personal gynecologist. In addition, the male partner may be referred to a urologist for basic infertility evaluation.

In cases of persistent infertility, however, patients increasingly are seeking out treatments by primary care physicians who specialize in infertility services, such as gynecologists and urologists who are often part of a group practice or infertility clinic. These are usually identified by one of the following means:

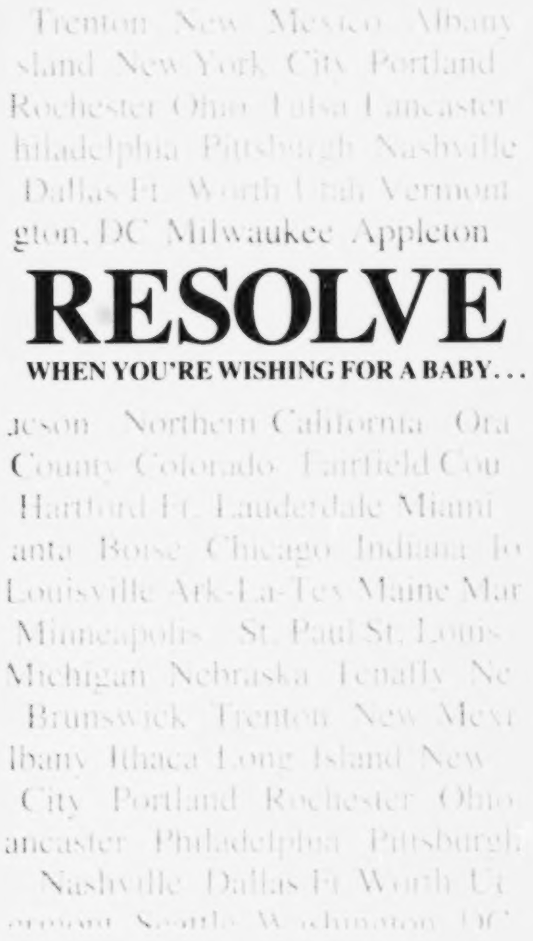
- referral by personal gynecologist or urologist to an associate in a group practice who is an infertility specialist;
- referral by gynecologist, urologist, or personal physician to the nearest medical school, large medical center, infertility clinic, or group practice;
- referral to a particular physician or clinic by organizations like Resolve (see box 6-A), a national infertile-couple support group that maintains a referral service in its local chapters; or
- other methods, such as referral by other infertile couples, national or local medical societies or groups, advertisements, or media coverage of babies born from new reproductive technologies.

Since infertility problems can involve both men and women, infertility is best diagnosed and treated with a team approach, spanning several specialties in medicine such as gynecology, urology, andrology, endocrinology, and reproductive tract microsurgery. Many medical schools, large medical centers, and group practices have infertility treatment programs that employ, or have a close consulting relationship with, a variety of specialists. Because of the psychological aspects of undergoing treatment and accepting the results of these diagnostic procedures, some infertility programs make psychologists or counselors available to the patients (see table 6-1). Comprehensive infertility practices usually include:

- a gynecologist who specializes in reproductive endocrinology (hormonal control of reproduction) or reproductive tract surgery,
- a urologist or andrologist who specializes in male infertility conditions or reproductive tract surgery, and
- a genetic and psychological counselor.

Although the presence of these specialists does not guarantee the success of an infertility treatment program, and much successful infertility diagnosis and treatment is administered by personal gynecologists, the more complex the factors contributing to a couple's infertility are, the greater the chance they will benefit from a broad range of experts.

Box 6-A.—Resolve, A Nationwide Support Network for Infertile Couples


Trenton New Mexico Albany
sland New York City Portland
Rochester Ohio Tulsa Lancaster
hiladelphia Pittsburgh Nashville
Dallas Ft. Worth Utah Vermont
gton, DC Milwaukee Appleton
RESOLVE
WHEN YOU'RE WISHING FOR A BABY...
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Hartford Ft. Lauderdale Miami
anta Boise Chicago Indiana Io
Louisville Ark-La-Tex Maine Mar
Minneapolis St. Paul St. Louis
Michigan Nebraska Tenafly Ne
Brunswick Trenton New Mexi
lbany Ithaca Long Island New
City Portland Rochester Ohio
ancaster Philadelphia Pittsburgh
Nashville Dallas Ft Worth Ut
Seattle Washington DC

SOURCE: Resolve Inc., 5 Water St., Arlington, MA 02174

Resolve, Inc., a nonprofit membership organization, was founded in Boston, MA, in 1973 by Barbara Menning. Menning was diagnosed infertile and found herself without emotional support and needing quality medical care. Meeting informally with friends and acquaintances who were also infertile, she began to write and speak about the issue.

By 1976, five groups in other parts of the United States had been formed, offering medical information and emotional support. In 1978, a small Federal family planning grant enabled Menning to rent office space, hire an assistant, and train family planning staff. By 1981, there were 35 affiliated, volunteer-run Resolve chapters across the United States. The Massachusetts office began to function as a clearinghouse for information and was responsible for the chapter network.

Today, 47 affiliated chapters offer monthly programs, telephone counseling, formal support groups, and medical information to infertile couples. The national office, financially supported by Resolve memberships and sale of literature, produces written medical information used by chapters and members, a national listing of specialists used by Resolve to refer patients to appropriate medical care, and information on programs that perform IVF or gamete intrafallopian transfer.

The staff of the national office are responsible for supervising chapters, initiating and responding to media inquiries, and providing public education on infertility to consumers and associated professionals. To date, Resolve has sponsored over forty 1-day conferences for infertile couples in major U.S. cities.

SOURCE: Office of Technology Assessment, 1988.

PATIENT HISTORY

A complete health history taken from both partners of an infertile couple is probably the single most important diagnostic tool the caregiver can employ. A complete patient history includes information about each partner's education, employment, personality, stimulant and substance use, medications and treatments, nutrition and diet, exercise, immunizations, medical history, surgical history, family history, psychological history, and sexual history.

Information obtained in this critical initial stage of the examination often provides important insights into the causes of a fertility problem. Clues derived from the details of an individual's personal, familial, and occupational background and the couple's sexual interaction can preclude the need for laboratory tests or complement their results. Questions, for example, about coital frequency and technique (e.g., use of vaginal lubricants) may indicate that these variables are the source of a

Table 6-1.—Counseling Opportunities

Mechanism of psychological support	Advantages	Disadvantages
Infertility clinic:		
Infertility clinic staff	No extra cost Clinic staff familiar with in-house procedures, may be able to be sensitive to likely emotional reactions	May be distant from patient's home, thereby presenting logistical difficulties Patient may not wish psychological information in records Expressions of emotional needs usually limited to specific clinic procedures
Infertility clinic consultant	Counseling professional available when cases of extreme emotional distress are noted	Professional alerted only after the patient is clearly overwhelmed, thereby being more reactive than preventive in counseling response
Professional counselor on staff at infertility clinic for orientation and counseling when requested	Preventive approach that includes orientation to clinic procedures, possible emotional impact of diagnosis, and referral to appropriate support groups or community services	Emphasis is on initial visit with patient, but the responsibility for future or ongoing contact rests with the patient
Professional counselor on staff at infertility clinic for orientation and regular contact with all patients to monitor emotional coping with diagnosis and treatment	Preventive approach includes orientation to clinic, possible emotional impact of diagnosis and treatment, short-term counseling, referrals to community services, and offer of a clinic support group	May be perceived as intrusive, or unnecessary; patients may resent efforts to make counseling mandatory
Community settings:		
Counselors in community	Counselor can work cooperatively with other members of the medical team Sliding fee scales Located in patient's community	Waiting lists at many agencies Few counselors have in-depth knowledge about infertility
Community support group	Low or no cost Reduces feelings of isolation	Individual needs may be submerged to group priorities
Telephone hot line	Offers privacy and anonymity	Counselors not likely to be knowledgeable about infertility
Counselors in private practice	Wait less lengthy than at community counseling agencies Patient chooses specific counselor	Costs may be high, although insurance may cover part or all
Religious leader	No cost Can address spiritual issues	Affiliation with religious institution may be necessary May be doctrinal objections to treatment chosen Few clergy knowledgeable about infertility

SOURCE: Office of Technology Assessment, 1988.

couple's inability to conceive. It is important, for instance, for the caregiver to ascertain whether the couple has experienced any form of sexual dysfunction (e.g., male impotence or erectile dysfunction), whether the couple engages in intercourse coincident with the woman's ovulation, and whether either partner has successfully reproduced with the present or any previous mate.

The sexual history, like any other part of the health history, is taken to produce information that may bear on the couple's fertility problem

(12). When a sexually transmitted disease is suspected, patients must often describe sexual preference, numbers and regularity of sexual partners, and any symptoms of sexually transmitted disease that partners may have exhibited. The information contained in a comprehensive sexual history may quickly pinpoint the source of fertility problems.

PHYSICAL EXAMINATION

Physical examination seeks evidence of physiological or anatomical bases for infertility. Standard health parameters (e.g., height, weight) and cardiovascular and neurologic function (e.g., blood pressure, strength of pulse in lower extremities, reflexes, pelvic sensation) are measured and particular attention is paid to the genitals and any anatomical abnormalities.

Male

The physical exam verifies the presence and structural adequacy of the various components of the genital tract (e.g., vas deferens, prostate, epididymis). Particular structural abnormalities associated with impaired fertility are sought (e.g., hernia, varicocele (varicose veins associated with the testes), or hypospadias (opening of the penis on the underside)). In addition, the size and volume of the testes are measured, as testicular atrophy is an indication of reduced sperm supply.

Female

Although the gonads are not external in the female as they are in the male, secondary sex characteristics (i.e., breast development, hair and fat distribution) are observable and provide an important indication of hormonal secretion and response. Excessive facial or body hair, for instance, may be the result of an excess of male hormones in a female.

A thorough pelvic examination, including palpation of structures throughout the genital tract, may identify infection, tumors, adhesions, or other abnormalities contributing to reproductive difficulties. Considerable information about internal pelvic structures can be obtained by means of palpation. An experienced physician can feel the size and shape of the uterus (which may have no bearing on fertility potential) and can check for the presence of any leiomyoma tumors (also known as fibroids). Leiomyomas, common in women over age 35, can sometimes interfere with implantation of the embryo or in rare instances cause miscarriage.

The pelvis is palpated for adhesions, rubbery bands of scar tissue that remain from previous infections or surgery. Adhesions that encapsulate the uterus, tubes, or ovaries can compromise the function of these organs. Small endometrial growths that are enough to cause infertility cannot, however, always be detected on manual exam. And there is no way to tell from a pelvic exam if the oviducts are open or closed. Overall, if the pelvic exam is normal, the probability of physical obstruction to pregnancy is reduced.

TECHNOLOGIES FOR EVALUATION OF REPRODUCTIVE STATUS

The evaluation of the infertile couple is a complex, time-consuming process. Since some infertility can be attributed to idiopathic (unknown) causes, the diagnostic process can result in much frustration for both the physician and the patients. Most procedures are designed to evaluate the function of a single physiological or anatomical aspect of reproductive function. In some cases, once an isolated abnormality is discovered, further diagnostic evaluation may not be pursued. This can be misleading if the infertility has more than one contributing factor.

In addition, a single determination of specific variables in the diagnostic evaluation can be misleading, since many of the physiological parameters assessed by these procedures, such as semen analysis and the post-coital test, can vary considerably over time.

A standard infertility workup (see box 6-B) may differ considerably from physician to physician, but the following procedures are most commonly followed:

- couple's history and physical exam,
- semen analysis,
- basal body temperature charts and other menstrual cycle mapping,
- cervical mucus evaluation,
- hormone assays,
- post-coital test,
- immunologic evaluation,
- endometrial biopsy,
- hysterosalpingogram,
- laparoscopy,
- hysteroscopy, and
- hamster-egg penetration assay.

Box 6-B.—Undergoing Diagnostic Procedures for Infertility

Undergoing diagnostic procedures can often be unpleasant. Women are likely to feel probed and manipulated, and repeated trips to the physician's office may begin to affect personal and professional life. Men may need to supply several semen samples. Masturbation in a physician's office may feel ridiculous or embarrassing. Men may find the process of having sperm counted and scored disconcerting. In addition, men may suffer from a great deal of helplessness and guilt for being the one having a much less invasive diagnostic process.

A post-coital test involves visiting the physician within a few hours of timed intercourse so that the woman's cervical mucus can be examined to determine how sperm interact with the vaginal and cervical environment of the woman. The demands of the pending doctor's appointment may make sex unpleasant for either partner. The man must achieve erection and ejaculation on schedule, and the surrounding tension may result in temporary impotence. The same reaction may occur when a couple has charted the woman's basal body temperature to determine ovulation. Once again partners may feel pressured to have intercourse on a schedule unrelated to sexual desires. This problem presents itself as a midcycle pattern of sexual dysfunction. Both partners may dislike having to reveal the intimate details of their sex lives, particularly at a time when that has been disrupted and distorted by the needs of the diagnostic workup.

If a couple are told that their infertility is caused by a problem for which there is no treatment, their psychological response almost universally resembles that of mourning a death. A couple learning that there is a treatment are likely to feel relief and hope. However, these feelings may not be based on an accurate perception by the couple of what lies ahead. In addition, the couple may also feel apprehensive of the cost, the inconvenience, the discomfort, and the risks associated with many treatments. If their infertility is due to repeated miscarriages, rather than an inability to conceive, they may dread the prospect of risking the loss of more pregnancies.

The couple who receive a diagnosis of unexplained infertility enter a psychological limbo. For some, the diagnosis of idiopathic infertility begins a series of new visits to infertility specialists; for others, it begins mourning, denial, anger, and grief, without final acceptance. The couple may feel out of control, and with medical professionals also baffled as to the cause of their infertility, the couple enter what is often a lengthy period of intermittent mourning, and efforts to "try again."

Secondary infertility (the inability to conceive after having at least one biological child) engenders surprise, followed by frustration, as a couple once in control of reproduction find that fertility now eludes them. When such couples express sadness about their inability to conceive another child, their pain is often discounted by others as they are reminded that they are, in fact, already parents. Couples with secondary infertility may find themselves overly preoccupied with the child they have, as all their hopes rest on his or her accomplishments and good health.

SOURCE: Office of Technology Assessment, 1988.

Diagnostics: Female Infertility

There are essentially three types of diagnostic technologies to evaluate infertility in women: over-the-counter products, laboratory-based methods, and physician- and hospital-based methods and procedures. In addition to the well-known advances made in laboratory- and physician-based infertility treatment technologies, the market for patient-use products and devices distributed mostly over the counter has grown rapidly. These products increasingly allow informed infertile patients to use on their own some basic infertility diagnostics and treatment methods.

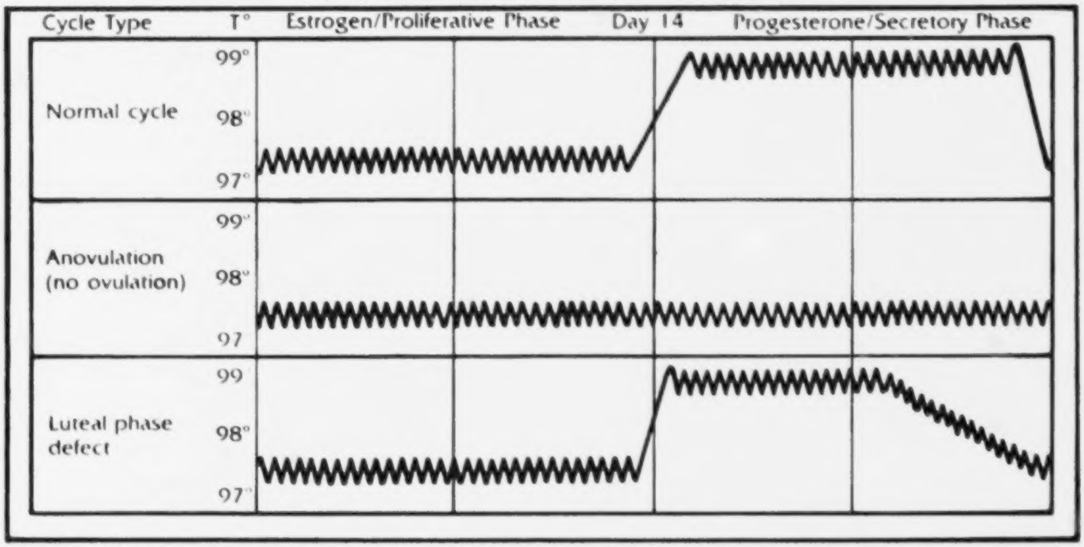
Not all the procedures described here would routinely be used in each diagnostic workup. If patient history, for example, indicated multiple episodes of a sexually transmitted disease, then investigation for tubal obstruction would be indicated, such as a hysterosalpingogram (an x ray of the uterus and fallopian tubes).

Basal Body Temperature

The recording of basal body temperature (BBT) is one of the oldest and most popular methods for predicting ovulation. This procedure relies on the characteristic changes in basal (resting) body temperature during the menstrual cycle (see figure 6-1). These alterations in temperature are a result of changes in the hormonal output of the ovaries. During the preovulatory phase (usually 14 days in regular, average cycles) of a menstrual cycle, when estrogen levels are rising, the BBT remains at resting level, approximately 98.0° F. When ovulation occurs, estrogen levels decline and progesterone levels rise, which causes an upward shift in BBT to 98.4° F or higher. (There may also be a slight decrease in BBT immediately before the upward shift to 98.4° F. This small decline may coincide with ovulation.)

Since preovulatory temperature values may vary among women, it is the change in temperature rather than the absolute reading that is important. The BBT usually remains elevated throughout the remainder of the cycle, returning to 98.0° F at the onset of the next cycle (38). By taking body temperatures daily, the menstrual cycle can often be charted and subsequent ovulations pinpointed to within a 4- to 6-day period. If BBT does not increase during a cycle, this indi-

Figure 6-1.—Basal Body Temperature Charts



Typical basal body temperature patterns that indicate normal ovulation (top), ovulatory failure (middle), or ovulation with luteal phase defect (bottom).

SOURCE: J.H. Bellina and J. Wilson, *You Can Have A Baby* (New York, NY: Crown Publishers, Inc., 1985).

cates that ovulation has probably not taken place and progesterone levels remain low.

As part of the infertility workup, the BBT has the greatest value with women who have average length (28 days), regular cycles. Although some clinicians find the BBT to be an inaccurate indicator that the preovulatory surge of luteinizing hormone (LH) and ovulation have occurred (7), others find it useful for pinpointing 4 to 6 days during which ovulation is likely to occur during subsequent cycles (38).

Another way to predict ovulation is the calendar method, which relies on the regularity of a patient's cycle to indicate the period of fertility. After a woman has recorded the duration and days between her menstrual period over several consecutive cycles, she can get a general idea as to the timespan surrounding subsequent ovulations. This method relies heavily on the regularity of an individual's cycles, since no other indicators besides past history are employed to pinpoint ovulation. When used to predict the fertile period of a cycle for means of birth control, this method has a fairly high failure rate (8).

Hormone Monitoring

Several ovulation prediction kits are currently sold over the counter. These kits measure, in a semiquantitative manner, the midcycle increase of LH, the hormone that causes ovulation under normal circumstances. The onset of the midcycle LH increase precedes ovulation by an average of 32 to 36 hours (20). This change in LH secretion is quickly reflected in the urine, making measurement of urinary LH useful in clinical applications to approximate the time of ovulation (24).

Most of these kits employ the enzyme-linked immunosorbent assay procedure. Antibodies that bind LH are immobilized on a small dipstick pad or form a dry coating at the bottom of a test tube. These antibodies (either pad or coated test tube) are incubated with the urine specimen and an additional reagent. When LH is present in the urine, a specific antibody-LH-reagent complex will form. When treated with another reagent, this complex develops a characteristic color indicating the presence of LH in the urine. If LH levels are high, the color that develops will be intense compared with a blank or reference indicator. In this manner, a qualitative prediction about the onset of the LH surge and the timing of ovulation can be made.

QUIDEL Q
QTest
FIRST RESPONSE
Ovulation Predictor Test
FIRST RESPONSE
OvuSTICK

Photo credit: Office of Technology Assessment

Home diagnostic tests

Measurement of another hormone, progesterone, as confirmation of ovulation, is quite routine in the infertility workup (17). This can be performed on a patient's blood or urine sample by laboratory personnel using complicated procedures such as radioimmunoassays to obtain a quantitative value, or in the physician's office or at home with rapid hormone test kits that provide semiquantitative values. Although observation of increased progesterone suggests that ovulation has occurred, failure to detect a rise of this hormone does not always indicate ovulatory failure but may suggest other hormonal problems such as luteal phase defect (50). In addition, failure of progesterone to increase to within the appropriate range may also signal a failure of ovulation. Furthermore, even in some instances where progesterone is in the ovulatory range, ovulation is not certain (49).

Other hormonal tests may also be performed to evaluate the function of the other endocrine systems. These hormones include prolactin, thyroid hormones, adrenal hormones, and gonadotropins (LH and follicle-stimulating hormone (FSH)).

Cervical Mucus Evaluation

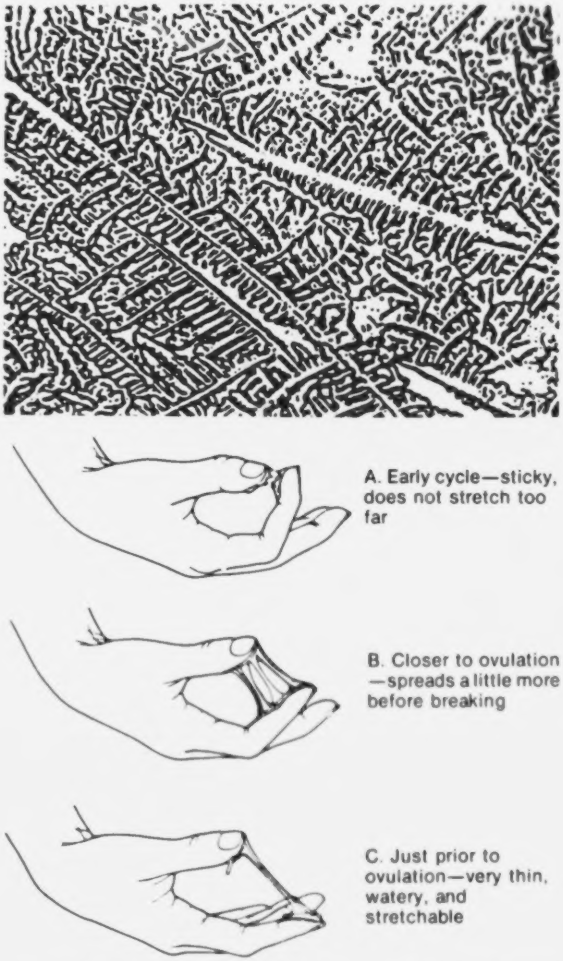
Another method for ovulation prediction relies on gross and microscopic examination of cervical mucus. As a result of changing levels of hormones during the cycle, cervical mucus undergoes consistent and dramatic changes in several of its physical properties. Under the influence of the high estrogen levels that precede ovulation, cervical mucus becomes thin, watery, salty, and stretchy (elastic). These first three characteristics can be evaluated by what is known as the fern test (see figure 6-2). When placed on a glass slide and allowed to dry, cervical mucus dries into a distinctive fern-like pattern. As ovulation approaches more ferning can be seen.

Likewise, the spinnbarkeit test evaluates the stretchiness of cervical mucus, which also increases under the influence of high estrogen levels. A small drop of mucus, obtained close to ovulation, is placed between two glass slides (or two fingers). When the slides are separated, the threading of the mucus that results should stretch 8 to 12 centimeters without breaking (see figure 6-2). If ovulation has already occurred, or there is ovulatory failure, then the mucus is scanty and thick.

In addition to these characteristics, cervical mucus should also be examined for the presence of cells or debris and proper pH (acidity or alkalinity), factors that can also affect fertility. The administration of fertility drugs such as clomiphene, for ovulation induction, can affect the characteristics of cervical mucus.

More sophisticated examination of the hormone-induced changes in the characteristics of these body fluids can contribute to ovulation prediction. One recently developed method relies on the documented changes in ion concentration (sodium and potassium) in saliva and vaginal mucus throughout the menstrual cycle (35). A handheld electronic device (CUE Fertility Monitor; Zetek, Inc., Aurora, CO) employs sensors that measure the electrical resistance of saliva and vaginal mucus. Because minute changes in the ion concentrations of these body fluids result in alterations of their electrical resistance, changes in electrical resistance of the saliva and vaginal mucus can be used to predict ovulation, possibly up to 7 days in advance (2).

Figure 6-2.—Cervical Mucus Evaluation Tests



A. Early cycle—sticky, does not stretch too far

B. Closer to ovulation —spreads a little more before breaking

C. Just prior to ovulation—very thin, watery, and stretchable

Two simple cervical mucus evaluation tests. Top panel shows the characteristic fern-like pattern (fern test) that results when pre-ovulatory cervical mucus dries on a glass slide. Bottom panel shows the characteristic stretchiness of cervical mucus during the pre-ovulatory period.

SOURCES: L. Speroff, R.H. Glass, and N.G. Kase, *Clinical Gynecologic Endocrinology and Infertility* (Baltimore, MD: Williams & Wilkins Co., 1978); S.J. Silber, *How Not To Get Pregnant* (New York, NY: Charles Scribner's Sons, 1987).

Endometrial Biopsy

Endometrial biopsy involves microscopic examination of a sample of endometrial cells obtained between days 22 and 25 (sometimes as late as day 26 or 27) of the menstrual cycle (assuming a regular, 28-day cycle). In the physician's office, a long hollow tube is passed through the cervix into the uterus and a small amount of tissue is scraped off the endometrium. By microscopic examination of these cells, the physician can date the endometrial lining in reference to the first day of the cycle. This dating of endometrial cells is accomplished by observation of the distinctive hormone-induced characteristics. The appearance of these cells changes daily under the influence of ovarian hormones (39).

During this stage of a normal menstrual cycle the endometrium is primed for implantation under the influence of progesterone, with the cells appearing secretory and spongy. If ovulation has not occurred or there is a luteal phase defect caused by inadequate progesterone secretion after ovulation, then the endometrial cells will not have the typical progesterone-induced appearance. If the characteristics of the endometrial cells can be dated to the appropriate day of the cycle (usually within 1 day), then normal ovulation and progesterone secretion have most likely occurred, suggesting normal ovulatory function.

Ultrasonography

Use of ultrasound in infertility evaluation and treatment has become increasingly important. This technique uses high-frequency sound waves that are transmitted to one area of the body and echoed or reflected back by internal organs and structures. From the resulting patterns of transmission and reflection, detailed outlines of the female reproductive system can be obtained. Ultrasound is particularly useful in evaluating development of ovarian follicles during spontaneous or drug-induced cycles (16,34). If development of one or more follicles is monitored, and the subsequent collapse of these follicles after release of the ova can be visualized, then there is a good indication that ovulation has taken place. Ultrasound determination of ovulation is best used in combination with BBT, cervical mucus, or progesterone measurement. In some instances, ultrasound can be useful for visualization of growths or abnormalities in ovaries or the uterus. In addition, this technology is used in oocyte retrieval for in vitro fertilization (IVF).

Hysterosalpingogram

The hysterosalpingogram (HSG) is a radiographic (x-ray) examination of the female reproductive tract. Radio-opaque dyes are slowly injected into the uterus while x rays are taken. As the uterus fills and the dye moves out into the interior of the fallopian tubes, the radiographs can pinpoint areas of occlusion, adhesions, growths, or abnormalities such as fibroids. In most cases of normal, healthy fallopian tubes, the dye fills the length of the tube and slowly spills out the far end into the body cavity (44). Some practitioners report therapeutic benefits from the use of oil-soluble rather than water-soluble dyes for HSG (15).

Hysteroscopy

Hysteroscopy provides direct visualization of the interior of the uterus. The physician can evaluate directly any abnormalities that may be present in the uterus such as fibroids, polyps, a septum, or adhesions such as a web of scar tissue covering the uterine opening to the fallopian tubes. During hysteroscopy the uterus is expanded with injection of carbon dioxide gas or a liquid. This aids in visualization of tissue through the eyepiece of the hysteroscope, a long, narrow, illuminated instrument that is inserted through the cervix into the uterus. In addition to direct viewing, surgical procedures can also be performed by an experienced surgeon through the operating channel of the hysteroscope. These procedures include biopsies, removal of polyps, septums, scar tissue, fibroids, and removal of lost intrauterine devices. Some uterine and tubal abnormalities that do not appear with HSG or laparoscopy can only be detected by hysteroscopy (32).

Laparoscopy

The laparoscope has become an essential tool in both the diagnosis and treatment of infertility (see figure 6-3). Laparoscopy, like hysteroscopy, allows direct visualization of the female reproductive tract through an illuminated long, narrow instrument. The laparoscope is inserted into the

Figure 6-3.—Laparoscope In Use for Laser Surgery

SOURCE: Martin M. Quigley, Cleveland Clinic, Cleveland, OH.

body cavity (usually through the umbilicus or naval) to view the outside (internal) surface of the uterus, ovaries, and fallopian tubes. To enhance the visualization of the peritoneal surface of these structures and assess patency of the fallopian tubes, a blue dye is often injected into the uterus and fallopian tubes, as in the HSG. To detect pelvic endometriosis, pelvic adhesions, and tubo-ovarian adhesions, the laparoscope is usually necessary. As in the case of the hysteroscope, surgical procedures can be performed through the operating channel of the laparoscope, including lysis of pelvic adhesions and ablation of endometriosis (13,23). In addition to its diagnostic value, the laparoscope is frequently used to retrieve oocytes for IVF or gamete intrafallopian transfer.

Post-Coital Test

A number of in vivo and in vitro procedures evaluate the interaction of sperm, semen, and cervical mucus. The oldest and most widely practiced of these techniques is the in vivo post-coital test (also known as the Sims-Huhner test), which can be performed in a physician's office. Although this simple exam is widely used in infertility evaluation, there is lack of standardization and consensus on how to interpret the results (14).

This method evaluates sperm transport mechanisms within the female reproductive tract by directly examining under a microscope the interaction of sperm and cervical mucus. It should be performed as close to ovulation as possible, since cervical mucus is most conducive to sperm transport at that time. As ovulation approaches, the couple is asked to abstain from intercourse for several days prior to the planned test. One or two days before ovulation, the couple are instructed to have intercourse 2 to 4 hours before arriving at the physician's office (some physicians believe 6, 10, or even 24 hours after intercourse is a better indication of sperm transport). By means of a catheter, one to three samples of mucus are taken from different areas along the length of the cervical canal.

These specimens are evaluated for ferning pattern, spinnbarkeit, pH, cellularity, and debris, and for the number, motility, and quality of sperm present in the mucus sample. When examined under a microscope, a count of fewer than five motile sperm per field for mucus taken from the highest level of the cervical canal (internal os) indicates an abnormal post-coital test (37). Since inaccurate timing of this procedure is the most important cause of an abnormal result, negative post-coital tests should always be repeated. The presence of dead or nonmotile sperm can indicate a hostile cervical mucus or poor semen quality, which should be followed up by additional testing.

Several in vitro methods are also used to evaluate the quality of sperm-cervical mucus interaction. In a method devised by Kremer (25), cervical mucus collected around the time of ovulation is drawn up into a capillary tube (thin glass tubing) and the tube placed in a reservoir of the spouse's semen. Under normal conditions, the sperm can be observed penetrating the column of cervical mucus in one direction only when observed under low power through a microscope. If the sperm fail to move a set distance over a specified period of time, then subfertility may be suspected.

A variation on the Kremer method uses a commercially available preparation of small flat glass tubes filled with bovine cervical mucus (Pene-Trak™, Serono Diagnostics). Because of biochemical similarities between human and bovine cervical mucus, human sperm migrate up the Pene-Trak™ tube in a manner similar to their behavior when exposed to human cervical mucus. After a given period of time, the tube is examined under a microscope and the distance the sperm have penetrated the mucus column is measured. As with the Kremer method, failure of the sperm to move a minimal distance over a given period of time suggests an infertility problem (3,36). However, this test is not a substitute for human mucus in clinical testing (40).

Sperm Antibody Evaluation

Antibodies to sperm may be present in a significant portion of infertile couples. The exact extent or importance of these antibodies is unclear. However, some experts believe that antibodies can impair fertility by:

- impeding sperm penetration of cervical mucus,
- decreasing transport and viability of sperm in the oviducts,
- inhibiting sperm penetration of the ovum through blocking of possible receptor sites, or
- interfering with the normal postfertilization development of the fertilized ovum.

Antibodies are most readily diagnosed by examination of the post-coital test for sperm-cervical mucus interaction, gelatin agglutination tests, sperm immobilization test, or the immunobead test (4). With improved sensitivity and better detection of minute quantities of sperm antibodies, diagnosis of immunological factors in infertility will most likely increase.

Diagnostics: Male Infertility

Since less is known about male than female reproductive physiology, methods to diagnose and treat male infertility remain underdeveloped. The lack of comprehensive, standardized population data on various aspects of male infertility often results in a poor predictive value of test results. However, the present state of the art in male infertility diagnostic tests can supply at least some information about the ability of an individual to impregnate a female partner. Until additional research and data analysis are conducted, the diagnosis and treatment of male infertility will remain difficult.

Semen Analysis

The best diagnostic methods available to evaluate male infertility rely on the examination of a number of basic characteristics of sperm and seminal fluid (18). These parameters include the volume, pH, and viscosity of seminal fluid and the quantity, morphology, and motility of sperm in the sample. Basic sperm counts have been performed for many years as an index of male fertility, but recently developed tests can evaluate more subtle characteristics of the semen.

Since the evaluation of the semen has traditionally been subjective in nature, there is little standardization of diagnostic procedures. As a consequence, with the exception of total absence of sperm in the ejaculate, there remains less than total agreement over what constitutes a minimally adequate ejaculate necessary to achieve pregnancy (31,48). Introduction of computerized analysis may contribute to standardizing evaluation parameters and normal sperm characteristics between laboratories, and may provide objective criteria for measurements.

Since semen characteristics are subject to considerable fluctuation, semen analysis should be performed several times to ensure accurate evaluation of the ejaculate (46,48). The characteristics that can help in the diagnostic process include the following:

Appearance: The freshly collected semen sample should be whitish-gray in color. The presence of a bad odor or yellowish or red color may indicate infection or drug treatment (18).

Volume: Average semen volume ranges from 1.5 to 6 milliliters per ejaculate and varies depending on the period of abstinence between ejaculations. Even though smaller or larger semen volumes are often associated with infertility, the abnormal volume may not be the cause of the infertility but rather a symptom of some other condition. On the other hand, low semen volume may impair transport of sperm and high volume may dilute sperm density and decrease motility (18,31).

Ejaculate pH: Large deviations outside the normal pH range (7.2 to 7.8) can indicate inflammatory disorders of the prostate or seminal vesicles and may compromise fertility (18).

Liquefaction and viscosity: Usually the normal semen sample undergoes a transition from gel to liquid within 30 minutes of ejaculation. Liquefaction that does not occur or takes longer than 60 minutes may indicate prostatic disease and possibly trapped sperm contributing to infertility (18).

Sperm concentration: The concentration or count of sperm in the ejaculate is usually determined with the aid of a counting chamber such as a hemocytometer, a Makler chamber (30), or an automated device such as a Coulter counter or computer-assisted videomicrographic system. The actual number or concentration of sperm necessary to achieve pregnancy is still a matter of uncertainty. Statistical data and some clinical experience suggest that a sperm density of 20 million per milliliter is the lower limit of normal (29) but not the lower limit of fertility.

In general, 50 million to 60 million total sperm are usually necessary for fertilization (22). This assumes that the other characteristics of the sperm, such as motility and morphology, are good. However, men with sperm counts below this value may have reasonable chances for impregnation provided other characteristics of the ejaculate are normal (53). Since sperm density is a function of total semen volume as well as the number of sperm present, careful attention should be given to the natural fluctuation of semen volume and its influence on sperm counts.

Sperm motility: Although motility of sperm has traditionally been a more subjective evaluation than sperm number, many investigators believe it to be the most important indicator of semen quality (18,31). In the simple slide technique, a small sample of the specimen is placed on a slide, coverslipped, and viewed under the microscope. The percent of motile sperm in several fields is determined and the motility itself rated on a +1 to +4 scale. Using this subjective analysis, 60 percent or more motility is considered normal. With the use of more objective techniques such as videomicrography, this figure may be lower (31).

Computer-assisted semen analysis involves a video camera and recorder integrated with a microscope. Images of sperm in the sample are digitized and sequential images are stored. Most commercial systems provide data on the percentage of motile sperm, the swimming speed or velocity, the percentage of progressively motile sperm and their swimming speed, the percentage of rolling sperm, and the percentage of straight-swimming sperm. Some systems offer information on other sperm parameters, such as lateral head displacement and linearity of motion.

Overall, computer-assisted analyses provide more objective information about sperm motility and swimming patterns. However, the accuracy of these systems may be low with samples having low sperm concentrations or large amounts of debris. At this time only a small number of the objective measures made possible by these systems has been correlated with infertility parameters (4). However, as these objective measures become more widely used and more information is collected, a better understanding of sperm characteristics may be achieved.

Sperm morphology: Morphological evaluation of human sperm is complicated by the great natural variation in shape and size. This makes it difficult to predict which forms are associated with infertility and which are within the normal range. Normal sperm have symmetrically oval heads with stout midpieces slightly longer than the heads. Also present are long, gradually tapering tails, 7 to 15 times longer than the heads. Ratios of these various parameters appear to be important predictors of fertility (4). Human semen always contains some abnormal or immature sperm forms but increased percentages of these types can decrease fertility. Analysis of sperm morphology has not found widespread use in clinical practice. However, with computer-assisted video micrographic systems, morphological characteristics may become better diagnostic tools.

Fructose test: Fructose is a sugar produced by the seminal vesicles and present in the normal ejaculate. When sperm are present in the semen sample, fructose is almost always present as well. However, in cases where no or few sperm can be observed in the sample, the absence of fructose suggests blocked or missing seminal vesicles or ejaculatory ducts. The presence of fructose in a sample with few or no sperm indicates functioning seminal vesicles with possible blockage further down in the epididymis or the vas deferens, or testes that are not producing sperm. Fructose is detected in the semen by the addition of chemical reagents and heat. Color change to orange-red indicates the presence of fructose (31).

Agglutination and immunological disorders: Immunological disorders, such as sperm antibodies or bacterial infections, can cause sperm to bind together, or agglutinate. This condition is observed microscopically and may be tail to tail, head to head, mixed, or agglutination with cellular debris

(18). The presence of antibodies can also be detected by sperm/cervical mucus interaction characteristics during the post-coital test. The importance of this parameter remains unclear.

Infection screening: As part of the evaluation of semen, routine cultures are also taken to detect the presence of micro-organisms such as ureaplasma, chlamydia, and others. The precise role of these infections in infertility is unclear.

Hamster-Oocyte Penetration Test

The sperm/cervical mucus interaction tests evaluate sperm ability to navigate within the female reproductive tract. The hamster-oocyte penetration test examines sperm ability to penetrate the ovum once it has migrated into position. Usually, after capacitation for 18 to 20 hours, sperm are incubated with hamster eggs that have had their outer layer (zona pellucida) removed; normal human sperm usually penetrate these ova (52). If performed properly, there appears to be a correlation between the sperms' ability to penetrate the hamster and human oocytes. The reliability and significance of this test is controversial (10); however, further refinements and standardizations could make this an important diagnostic procedure for male infertility.

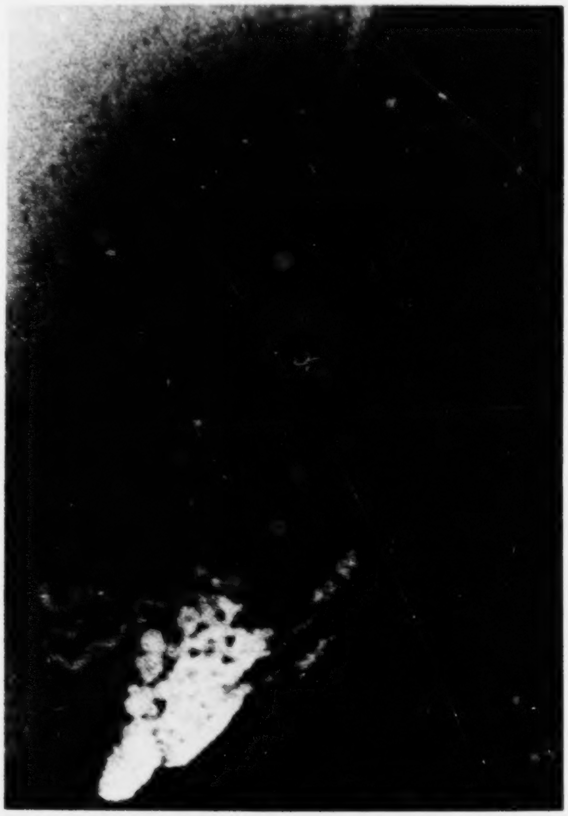
Testicular Biopsy

In men with normal size testes, no sperm in the ejaculate (azoospermia), and normal FSH, a testicular biopsy may be performed to determine whether the underlying defect is failure or blockage of the sperm-conducting system or the absence of sperm production in the testes. The biopsy is performed under local or general anesthesia. A small sample of testicular tissue is removed through an incision in the scrotum. The tissue is placed in a fixing agent and examined by a pathologist microscopically (9). The physician examines the specimen to identify the sperm cells at different stages of development that indicate normal, ongoing production of sperm. The absence or small number of particular cell types can help identify the infertility factor.

Radiography and Other Methods

Vasography and vesiculography are diagnostic methods that employ radio-opaque dyes and x-ray examination of the sperm transport ducts. A small incision is made in the scrotum and the vas deferens is exposed. Contrast dye is injected into the vas deferens or the ejaculatory duct and x rays are taken from various angles (see figure 6-4). This approach is particularly useful in pinpointing tubal obstruction in the male, since it gives an outline of the sperm transport system (48). Examination of the blood supply to the testis can also provide valuable diagnostic information in identifying varicocele. Venography or injection of contrast dye into the spermatic vein can verify a varicocele that may have escaped physical examination. Scrotal thermography, ultrasound, technesium scan, and Doppler test can also be useful for identification of varicocele and other vascular disorders of the male reproductive system (11,19).

Figure 6-4.—Vasogram



A retrograde vasogram of the vas deferens and epididymis demonstrating that the epididymis is one long, intricately coiled tube.

SOURCE: S.J. Silber, St. Luke's Hospital, St. Louis, MO, 1988.

Endocrine Evaluation

Since sperm production is critically dependent on hormones produced by the testes, such as testosterone, and on hormones produced at other sites in the body, such as the gonadotropins (LH and FSH), the hormonal workup is an essential part of male infertility diagnostic procedures. Basic endocrinological tests include blood assay for LH, FSH, and testosterone. Other hormones that may be examined are prolactin, thyroid hormones, estradiol, and adrenocorticoids. In addition, in a few instances the competence of the pituitary/testicular system is assessed by the luteinizing hormone-releasing hormone (LH-RH, also known as Gn-RH) test. This involves injecting LH-RH and carefully monitoring the gonadotropin and testosterone response to this stimulation (26,31).

Sexual Dysfunction

Sexual dysfunction should trigger a psychosexual evaluation by a trained psychologist or psychiatrist in the search for a cause for infertility. Physical examination of a patient who describes problems with impotence (erectile dysfunction) may include an assessment of erectile capacity. Determining the occurrence of erections during sleep (nocturnal penile tumescence, NPT) is considered one of the best means for distinguishing between physiologic and psychogenic causes of sexual dysfunction. NPT monitoring is best performed in the laboratory, where multiple sleep characteristics can be recorded. The principle of the monitoring device is a strain gauge worn around the penis, which indicates changes in penile circumference during sleep. Erectile function has also been evaluated using ultrasound evaluation of the blood supply to the penis during drug-induced erection. (For additional discussion of impotence, see ch. 7.)

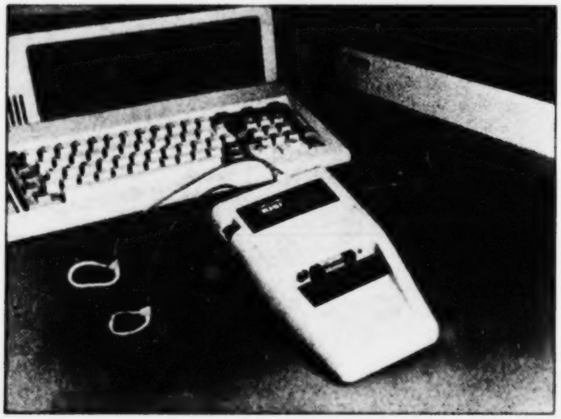


Photo credit: DACOMED Corp., Minneapolis, MN

Penile rigidity monitor

Retrograde ejaculation may be suspected when a patient fails to produce a semen sample or produces a small ejaculate. Diagnosis of this condition is most easily accomplished by observation of large numbers of sperm in the urine specimen taken soon after ejaculation. Full investigation of the etiology of this disorder may require a complete neurological assessment (18).

Risks of Diagnostic Procedures

Tests and procedures performed in any specialty of medicine have certain known (and unknown) risks associated with them. Some infertility diagnostic and treatment procedures also fall into this category. Although some of these risks have been documented in the medical literature, others remain unknown or unreported.

Most procedures performed as part of an infertility workup have relatively minor risks associated with them. For example, endometrial biopsy is considered a generally safe procedure. Possible side effects of this procedure include pain, bleeding, and uterine cramping. More serious complications of this procedure, although uncommon, can result from accidental uterine perforation. In addition, if this biopsy is inadvertently performed during early pregnancy, spontaneous abortion is possible (21,47).

Hysterosalpingogram is often a painful procedure. In some cases severe pain may require administration of analgesics. The major risks of this procedure include the spread of micro-organisms from cervix to upper genital tract or the reactivation of dormant pelvic organ infections. However, infection occurs in only a small percentage of women after HSG, usually those with a previous history of this condition (21,44,47). Other possible complications include lung emboli and respiratory distress, which can have severe consequences. In addition, the risks associated with small amounts of radiation exposure to the ovary are unknown (21).

It is not known if there is risk to the offspring from HSG inadvertently performed during early pregnancy. There is concern about radiation exposure of an early embryo; however, the dose of radiation from HSG is on the order of 1 rad or less. This amount of radiation appears unlikely to result in an increase in adverse pregnancy outcome (28). Whether or not HSG can dislodge an implanted blastocyst is uncertain but this possibility appears unlikely (47). In order to avert any theoretical risks to the early embryo, HSG is customarily performed prior to the anticipated time of ovulation.

Laparoscopy is a common procedure for both diagnosis and treatment of infertility. This procedure carries risks such as anesthesia complications, infection, or tissue damage, similar to those associated with other surgical procedures. The most common risk is post-surgical infection. Typical infection rates are two to three per thousand for laparoscopy. (6,41,42). Of these, most infections are superficial, involving the incisions in the abdominal wall, although more serious infections can occur.

Other risks associated with laparoscopy include injuries to intra-abdominal organs. These are associated in diagnostic procedures with introduction of instruments through the abdominal wall. In conventional laparoscopy, the initial step in the operation is the establishment of a space around the reproductive organs by placing two or three liters of gas (often carbon dioxide or air) into the peritoneal cavity. This gas lifts the abdominal wall off the internal organs permitting more space for insertion of instruments and a clearer view of the intra-abdominal contents. The placing of the gas is often accomplished with a long needle, placed into the abdomen. Misplacement of the needle into intestinal or blood vessels may be associated with severe injury to these organs and the need for major surgical repair (47).

In laparoscopic procedures where intra-abdominal surgery is also performed, another opportunity for internal organ injury exists—thermal injury to the intestine during cauterization of the fallopian tubes for sterilization. A final source of complications during laparoscopy is the gas used to lift the anterior abdominal wall from the viscera. Gas-related shoulder discomfort after surgery is common, but serious complications are rare. Gas emboli may be associated with exceptionally large volumes or pressures of gas or with accidental injection of gas into a vessel.

Complications of hysteroscopy can include those attributable to the distending media and those associated with surgery, such as infection, anesthesia-related complications, or uterine perforation. Carbon dioxide used as the distending medium can cause hypercarbia, acidosis, and cardiac arrhythmias (43), although a review of 1,500 cases in which carbon dioxide was used showed no complications and there were no changes in pH, pCO_2, or electrocardiogram in 40 monitored patients (27). The insertion of instruments into the uterus introduces the possibility of perforation of the uterus. Pelvic infection after hysteroscopy is unusual although the incidence of this complication appears to increase if surgical procedures are performed (5,51).

Since far fewer diagnostic tests exist to evaluate male infertility problems, the known risks of male infertility workup are fewer. For example, there are no known hazards associated with semen analysis, the most common and important diagnostic procedure for males. However, invasive techniques such as testicular biopsy can result in bleeding, infection, and possibly trauma to the testis causing transient decrease in function (47). Injection of radiologic contrast material into the vas deferens in vasography has been used to visualize portions of the male genital duct system. This procedure carries with it the possibility of injury to the vas or epididymis as well as exposure to x rays (45).

The degree of risks associated with any of these diagnostic procedures (as well as all medical procedures) are profoundly influenced by the skill with which they are performed. Relatively safe procedures can result in severe complications if performed by inexperienced and unqualified professionals. On the other hand, physicians with appropriate skill and training can provide safe and effective infertility workups, even if complicated procedures are required. In addition, although certain risks to these procedures are known and can be avoided, there may be additional unknown risks.

SUMMARY AND CONCLUSIONS

Although an individual's reproductive capacity can be estimated with several methods, fertility is a product of the specific interactions of a couple. Evaluation of infertility, therefore, must consider the couple as a unit.

A thorough assessment of fertility extends beyond an evaluation of reproductive organs and reproductive cells (sperm and eggs). Physical examination of the infertility patient, for example, includes assessment of circulatory, endocrine, and neurologic function. Oral or written history-taking collects a broad range of medical and lifestyle characteristics that may influence reproductive health.

Examination of a male patient is simplified by the fact that his reproductive organs and germ cells (sperm) are readily accessible. However, this ease of accessibility is not accompanied by better and more varied infertility treatments in the male. This is due, in part, to a continued lack of knowledge about male reproductive physiology. Although semen analysis does permit evaluation of several aspects of male reproductive function and of semen quality and quantity, much uncertainty remains about what parameters can reliably differentiate sperm capable of fertilizing an egg from those that are not.

Female reproductive health can be estimated through a variety of indirect indicators (e.g., menstrual regularity, hormone levels, properties of cervical mucus) and direct methods (e.g., tissue biopsy, laparoscopy, ultrasound imaging). These tests can often pinpoint easily treatable conditions or, in contrast, disorders so severe that successful pregnancy is highly unlikely. Even with the current sophisticated level of diagnostic technology, however, no fertility test can positively predict a woman's ability to conceive or maintain a pregnancy.

Present diagnostic methods are able to identify a factor contributing to infertility in the majority of cases. In cases of idiopathic (unexplained) infertility, diagnostic technologies have failed. Techniques that consider the interaction and compatibility of a couple as a unit (e.g., interaction between sperm and cervical mucus) provide some of the best predictors of a couple's ability to have a child. More basic and applied research are needed in this area. Until more is known about reproductive dysfunction, successful reproduction will remain the only absolute verification of a couple's fertility.

Like many medical procedures, some tests used in an infertility diagnostic workup have certain risks associated with them. These risks are often similar to those associated with other medical and surgical procedures and can depend on the skill and training of those performing the procedures.

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Chapter 7

Treatment of Infertility

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Chapter 7

Treatment of Infertility

Sophisticated new technologies, such as in vitro fertilization (IVF) and gamete intrafallopian transfer (GIFT), have recently been developed for the treatment of infertility. In addition to these new reproductive technologies, great progress has been made in the treatment of infertility with traditional medical and surgical approaches, such as drug therapy and reproductive-tract microsurgery and laser surgery. Although noncoital reproductive technologies have received much attention, the more traditional approaches currently account for the overwhelming majority of infertility treatments.

MEDICAL TREATMENTS

In this section, all nonsurgical procedures and practices are considered medical treatments. Artificial insemination and cryopreservation are considered separately.

Female Infertility

Medical treatments for female infertility administered by a health care provider can range from advice that assists a couple in pinpointing the time of ovulation to complex regimens of fertility drugs.

As described in chapter 6, the initial patient history and physical examination are important tools in identifying possible infertility problems or suspected factors contributing to it. Evaluating and maintaining good general health and nutrition can contribute significantly to reproductive function. Yet even in the case of robust general and psychological health, a fully functioning reproductive system may be lacking. As is true with all diagnostic procedures, infertility treatments can be a source of considerable anxiety about pain and outcome; the psychological well-being of the couple is a principal factor to consider during treatment (see box 7-A).

Ovulation Induction

Female infertility is often related to problems with the complex biological events surrounding ovulation. Disorders of ovulation include conditions such as amenorrhea (absence of menstruation), oligomenorrhea (scanty or infrequent menstruation, usually cycles longer than 35 days), or luteal phase defects (LPD) (failure of the endometrial lining of the uterus to develop properly after ovulation). The complete absence or irregularity of the menstrual cycle is the most obvious indicator of ovulatory dysfunction. In this case, further testing is needed to determine the exact site of the ovulatory problem—hypothalamus, pituitary, ovary, or elsewhere. Only when the origin of the dysfunction has been identified can appropriate treatment be administered.

It is not unusual, however, even in the presence of apparently normal and regular menstrual periods, for there to be underlying ovulatory failure. Ovulatory dysfunction without menstrual irregularity becomes apparent only after examination of basal body temperature (BBT) charts, serum progesterone levels, and endometrial biopsies. Although a number of therapeutic agents treat ovulatory dysfunction, the most commonly used are compounds known as fertility drugs. These include clomiphene citrate, human gonadotropins (human menopausal gonadotropin, follicle-stimulating hormone, human chorionic gonadotropin), gonadotropin releasing hormone, bromocriptine, glucocorticoids, and progesterone. The etiology of the dysfunction determines which treatment to use.

Clomiphene Citrate.—The most commonly prescribed fertility drug is clomiphene citrate (CC). Clomiphene is a nonsteroidal estrogen-like compound that binds to estrogen receptors in the body. Although its mode of action in inducing ovulation remains unclear, it most likely blocks the actions of the natural estrogens in the hypothalamus (36).

Box 7-A.—Psychological Effects of Undergoing Treatment

The emotional effects of medical and surgical treatments for infertility are often a problem, particularly for women. Clomiphene citrate, for example, may prolong the menstrual cycle and thus falsely increase the hope of a pregnancy. Other drugs cause weight gain, nausea, acne, hot flashes, and mood swings.

Some fertility drugs create a risk of multiple conceptions. Although many couples welcome twins after a period of infertility, the increased risk of miscarriage, birth defects, low birth weight, and complications during delivery are worrisome, and some couples hesitate at the thought of raising several children at once.

Many people find themselves nervous about surgery, fearing both the procedure and their future efforts to achieve pregnancy once the procedure is over. Those who take time away from work for surgery and recovery will need to decide whom to tell and how much to tell about the reason for the surgery, and how to manage lost income as well as expenses not covered by insurance.

A couple using artificial insemination must adjust to achieving pregnancy noncoitally. The clinical atmosphere surrounding the insemination can be unsettling, and the man must produce a semen specimen while the woman waits. It is not uncommon for the male to be temporarily impotent. The woman is often concerned that she may not be ovulating on the day of the insemination, despite efforts to use home ovulation test kits accurately. Since about 50 percent of infertility clinics do not do inseminations on weekends, some couples feel frustrated that they have missed a potential insemination because of the rigidity of the clinic's schedule.

Couples using IVF must accept its relatively low success rate and high cost; tolerate the medication prescribed for the woman; be able to travel to the clinic; bear the expense of lost work time, travel, and hotel stays; endure the anxiety of waiting to see whether fertilization occurs; and wait two anxious weeks to see if pregnancy ensues.

Some couples using artificial insemination by donor are put off by the thought of the woman carrying another man's baby. Together, they must decide whether they will tell others about the insemination. They may wonder whether their love for a child conceived with donor sperm will be any different than that for a child conceived in traditional fashion.

Couples hiring surrogate mothers are still so few that little has been written about their experiences. Nevertheless, all the problems experienced with artificial insemination by donor are likely to be present in analogous form. In addition, during the 9 months of pregnancy the couple will probably worry about whether the baby will ever really be turned over to them. Even if this happens, they may well worry whether complications will arise later, should the baby's biological mother ever regret her participation.

Infertile couples may also have difficulty making major decisions or changes in their lives. Job changes may not take place because the medical insurance is needed or a pregnancy is expected at any time. A new house may not be bought or a vacation may be skipped because of the expense and uncertainty of infertility. A couple's life can become controlled by infertility treatment.

SOURCE: Office of Technology Assessment, 1988.

It may also affect the function of the pituitary and ovaries (35,66,75). The end result is increased gonadotropin secretion and stimulation of the ovary. Clomiphene's use is primarily indicated for patients with oligomenorrhea caused by mild dysfunction of the hypothalamus or pituitary or by other conditions (66). To induce ovulation, this drug is usually given on the fifth day after the onset of menses and continued through day nine. With this regimen, ovulation is expected between days 14 to 18 of the cycle.

Gonadotropins.—In more severe cases of ovulatory dysfunction resulting from pituitary or hypothalamic shutdown, human gonadotropins can be administered to stimulate the ovary directly (36). This can be accomplished with either human menopausal gonadotropin (hMG) or human follicle-stimulating hormone (hFSH). These potent stimulators of ovarian function are extracted from the urine of menopausal women. They are usually used if an individual fails to respond to clomiphene citrate or other compounds.

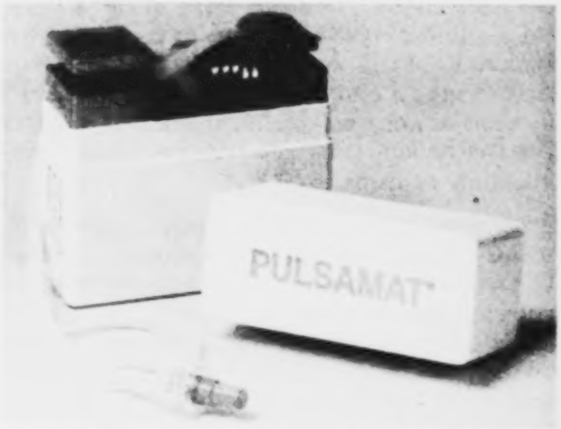
Administration regimens for gonadotropins can vary considerably depending on the nature of the ovulatory dysfunction, the other medications being given concurrently, and the preference of the individual clinician. Because these hormones bypass the endogenous gonadotropin control system and act directly on the ovary, careful monitoring of their potent effects on the ovary must accompany their administration. This is accomplished by daily measurements of the amount of estrogen produced by the ovary under the influence of these compounds, and by monitoring the growth of ovarian follicles with ultrasound (52). As the ovarian follicles containing the ova (eggs) develop under the influence of these two hormones, ultrasound (and estrogen measurement) allows the physician to determine if the follicles are large and mature enough for ova release.

The actual release of the ovum is brought about by injection of an additional hormone, human chorionic gonadotropin (hCG), which is similar to luteinizing hormone (LH). The high hCG levels resulting from the injection mimic the actions of the natural LH ovulatory surge, causing rupture of the follicle and release of the ovum.

Gonadotropin Releasing Hormone.—In cases of severe hypothalamic dysfunction with intact pituitary and ovarian function, induction of ovulation with gonadotropin releasing hormone (Gn-RH) has been successful (76). Gn-RH is the hormone released from the hypothalamus that in turn causes the secretion of gonadotropins from the pituitary gland. In cases of hypothalamic dysfunction, Gn-RH release is impaired or absent. With the use of a portable infusion pump, Gn-RH can be administered in such a way that it mimics the natural release pattern (see figure 7-1). This promotes secretion of gonadotropins from the pituitary, follicle development, and subsequent natural ovulation. Although officially only available for ovulation induction in clinical trials at present, this approach of mimicking endogenous hormone patterns may become more widely used upon approval by the Food and Drug Administration.

Bromocriptine.—Bromocriptine is commonly used in cases of infertility associated with oversecretion of prolactin. Prolactin, a hormone responsible for normal milk production, can also disrupt regular ovulatory function. In women with hyperprolactinemia (high levels of prolactin, often caused by a hormone secreting tumor) or transient elevations of prolactin, daily administration of bromocriptine can lower blood prolactin levels. Bromocriptine is a synthetic compound that interferes with the pituitary's ability to secrete prolactin. Ovulation usually returns after 6 to 12 weeks of daily treatment (66).

Figure 7-1.—Portable Infusion Pump



Infusion pump is worn continuously and delivers gonadotropin releasing hormone intermittently either subcutaneously or intravenously.

SOURCE: Ferring Laboratories, Inc., Suffern, NY, 1988.

Glucocorticoids.—Ovulatory dysfunction is often present in patients with adrenal disorders. Treatment of the adrenal condition with synthetic glucocorticoids (one class of hormones naturally produced by the adrenal glands) alone or in combination with other drugs can result in resumption of ovulatory cycles (17). This treatment can also be effective for the amenorrhea associated with polycystic ovaries (24).

Progesterone.—Luteal phase defect can also be treated with drugs, depending on the etiology. Treatment with progesterone, the hormone normally secreted in large quantities by the ovary after ovulation, can be an effective treatment for this condition (47).

Other Drug Therapies

Endometriosis can be treated with a variety of pharmaceutical agents. Even in severe cases, drug therapy is usually recommended prior to surgical intervention. Although many of these medical treatments prove effective in combating the symptoms of this disorder, the efficacy of these treatments for endometriosis-associated infertility remains uncertain (33,53). In addition, the precise role endometriosis plays as a mechanism for infertility remains unclear (53).

The most popular drug treatment for endometriosis is danazol, a synthetic derivative of testosterone. This compound acts to suppress normal gonadotropin secretion and thereby cyclic ovarian hormone production, and has a direct effect on the endometrium (5). The end result of these multiple actions is to produce a hormonal state, similar to that of chronic anovulation, that causes regression of endometriosis tissues (25). Danazol taken daily for periods of 4 to 6 months or longer is the usual course of treatment. After this time, evidence of endometriosis is often reassessed by laparoscopy.

Other drug therapies include progestogens, estrogens, Gn-RH blockers, or combinations of these compounds.

Uterine and Cervical Infections

Infections of the male and female reproductive tract have been increasingly recognized as a major contributory factor of infertility. Although infectious organisms such as gonorrhea have long been associated with severe reproductive tract disorders, micro-organisms such as chlamydia and mycoplasma are now also associated with reproductive-tract infections that lead to infertility. These infections are associated with pelvic inflammatory disease and cervical or uterine factors in infertility.

Treatment of chlamydia, gonorrhea, and mycoplasma is usually accomplished with a 7- to 10-day regimen of antibiotics such as tetracycline, erythromycin, or doxycycline. Adequacy of treatment must be verified by followup laboratory cultures 3 to 6 weeks after treatment (59).

Immunological Disorders

The role of antibodies to sperm and semen in the etiology of infertility has received increased attention. A number of studies have shown an increased incidence of sperm antibodies in both the male and female partners of infertile couples compared with normal fertile couples (60). These antibodies are most likely responsible for abnormal sperm and cervical mucus interactions that inhibit or prevent fertilization from taking place.

A number of treatments for this condition have been used. When the antibodies to the sperm appear in the female partner only, condom therapy may be beneficial. Use of condoms for 6 months has been reported to reduce the quantity of sperm antibodies in the female (31). This may lead to normal sperm-mucus interaction when use of a condom is discontinued during subsequent fertile periods. However, this practice is no longer widely used. Glucocorticoid therapy is also effective in

Photo credit: Repro-Med Systems, Inc., Middletown, NY

Water-cooled scrotal jacket.

suppressing the production of these antibodies in both the male and female. It has been reported that once antibody levels have been reduced, pregnancy rates increase (37). In addition to the above procedures, which act to reduce the production of sperm antibodies, intrauterine insemination with the husband's washed sperm, donor insemination, IVF, or gamete intrafallopian transfer may be appropriate.

Sexual Dysfunction

Several sexual dysfunction conditions are associated with infertility in the female. The most common is vaginismus, a condition in which penile entry into the vagina is impossible or extremely difficult because of an involuntary contraction of the muscles around the outer third of the vagina. This condition can be caused by past sexual assault, previous traumatic pelvic examinations, anxiety, painful intercourse due to chronic vaginitis or lubrication disorders, or other psychological and organic problems. If an organic cause can be treated or ruled out, and the condition continues, then treatment for this disorder usually entails simple, passive dilatation of the vagina with associated desensitization techniques. This treatment is effective in nearly all patients, allowing normal intercourse to commence or resume (23).

Male Infertility

Medical treatment for male infertility is not as extensive as treatment for female infertility. Although a number of characteristics of semen and sperm can be assessed by semen analysis, the treatment of abnormalities remains elusive.

Environmental Factors

Environmental factors appear to be closely associated with some forms of male infertility. Excessive heat to the testes and exposure to toxic chemicals (e.g., in the workplace) have been associated with reduced sperm production and viability (72). Routine cooling of the scrotum, as with a water-cooled scrotal jacket, may increase sperm quality (78).

Hormone Therapy

Hormone therapy in male infertility is most beneficial in cases of gonadotropin deficiency. Human menopausal gonadotropin administered in combination with human chorionic gonadotropin for periods of up to 6 months can be an effective treatment for some types of azoospermia. Clomiphene citrate and tamoxifen can stimulate natural gonadotropin secretion, thereby increasing stimulation of the testes and subsequent spermatogenesis. Long-term treatment with gonadotropin releasing hormone delivered by portable infusion pumps has been reported to induce spermatogenesis in patients with hypothalamic deficiencies (73).

Testolactone, a drug that reduces the production of estrogen, has also been used for treatment of male infertility, although its efficacy in such treatment has been challenged (14). Numerous other kinds of drugs have been administered in cases of male infertility, including testosterone (low and high doses), corticosteroids, triiodothyronine, kinin-releasing agents, anti-prostaglandins, and vitamins C and E (45). Overall, the efficacy of drug and hormonal therapy in the majority of male infertility patients remains unclear.

Reproductive Tract Infections

Although infections of the reproductive tract are less common in the male than in the female, a patient's semen should be cultured in the laboratory to screen for the presence of a wide range of micro-organisms. Infections such as gonorrhea, chlamydia, mycoplasma, and others can be treated with appropriate antibiotics, depending on the patient's medication sensitivity. Prostatitis (inflammation of the prostate gland) can also be treated with antibiotic regimens for periods as long as several months.

Sexual Dysfunction

Sexual dysfunction as a contributing factor of infertility may be present in as many as 5 percent of infertile couples (56). Male patients with organic impotence may respond to hormone therapy, surgery to restore blood flow to the penis, or drug therapy that directly induces erections. In addition, erection and ejaculation may be induced by electrical or vibratory stimulation such as used in spinal cord injury patients (see box 10-A in ch. 10). Psychogenic impotence and premature ejaculation can be treated successfully with psychotherapy and behavior modification. Retrograde ejaculation can be treated with drugs or surgery depending on the etiology of the condition.

SURGICAL TREATMENTS

Female Infertility

Many different surgical procedures are used in the treatment of various disorders of the female reproductive tract. Only the procedures most commonly and widely used in the treatment of infertility are discussed here. These procedures can be roughly divided into two categories, traditional surgery (macrosurgical) and microsurgery. Traditional reproductive surgery techniques usually refer to surgery on large, easily visualized structures; microsurgical techniques entail fine, delicate surgical procedures performed with the aid of a microscope or other magnifying apparatus. Although some conditions may indicate the use of one approach over the other, there is often overlap between these approaches for any given treatment.

All these procedures are performed under general anesthetic and, with the exception of the use of the laparoscope, involve laparotomy. Laparotomy involves a larger incision in the abdominal wall than laparoscopy, to allow direct visualization of the reproductive structures.

Traditional Surgery

Infection, previous surgery, peritonitis, and pregnancy complications can all lead to adhesions, occlusion, and scarring of the female reproductive tract.

Adhesions are abnormal fibrous connections made between structures of the female reproductive tract that are not otherwise joined. These often occur in the ovary or fallopian tubes after inflammation or damage. This condition can impair fertility by severely restricting the movement of the fallopian tubes, thereby hindering ovum pickup from the ovary and transport toward the uterus. Removal of adhesions (adhesiolysis) is accomplished by electrocautery devices, dissection, or lasers. In the case of lasers, this may be accomplished via the laparoscope, although this approach is not common. Once adhesions are removed, tubal and ovarian motility can be greatly improved (64).

Pelvic inflammatory disease can often lead to a narrowing or occlusion of the distal end (closest to the ovary) of a fallopian tube—the ampulla and fimbria. A salpingostomy attempts to recreate the normal fallopian tube opening and fimbria function when complete occlusion has occurred. A fimbrioplasty corrects partial restriction, occlusions, or adhesions of the finger-like appendages of the fimbria so that normal movement can resume. These procedures are usually performed without magnification, although the microsurgical approach is likely to improve success. In addition, the carbon dioxide laser may be of some use in these procedures (46,62).

A surgical approach may also be warranted in cases of endometriosis that either do not respond to drugs or are severe. Endometrial tissue (implants) throughout the abdominal cavity can be removed by excision or cauterization. Recent attempts have employed the laser to vaporize implants. Again, as with distal tubal surgery, microsurgical techniques may greatly improve removal of endometrial tissue that may otherwise go undetected (53).

Microsurgery

The development of new and better microsurgical techniques in recent years has greatly improved the success of tubal surgery. The most common tubal microsurgical procedures involve excision and repair of scarring or damage at various points along the fallopian tubes. This is critical to ensure proper ovum transport down the fallopian tubes and passage of sperm in the opposite direction.

Scarring to the inside of the fallopian tube is most difficult to treat successfully since this condition usually involves not only narrowing or occlusion of the tube but also damage to the millions of cilia lining the tract. Extensive damage to these cilia, which help propel the ovum toward the uterus, severely impairs ovum transport.

With the aid of a microscope, fine surgical instruments, and much practice, a skilled microsurgeon can locate and excise the damaged portion of the tube. The two ends of the tubes are cleared of any material and then the inside of the tube (lumen) is rejoined and sutured together. Special care must be taken for proper alignment of the ends of the tube. Using this basic approach, various sections of the fallopian tubes can be repaired. Because the diameter of the tubes varies at different locations, however, removal of large lengths can make joining a larger diameter section to a much smaller diameter section technically difficult. In addition, depending on the extent and location of damage or scarring, the difficulty and success rate varies. Overall, the greater the length of fallopian tube left, the higher the rate of success at attaining pregnancy (63).

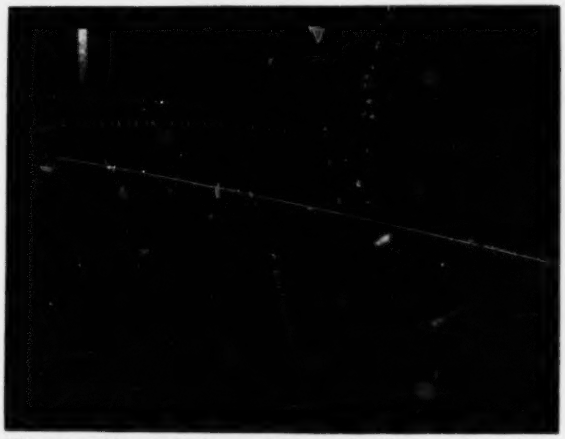
Success rates for these procedures depend largely on the skill and training of the individual surgeons. The overall success rate for this treatment of infertility should continue to improve as more surgeons become proficient at reproductive microsurgical techniques.

In Vitro Fertilization

In vitro fertilization is a highly sophisticated infertility treatment that involves obtaining mature oocytes through surgical procedures such as laparoscopy or through nonsurgical procedures such as ultrasound-guided oocyte retrieval. These mature oocytes are produced by natural ovulatory cycles, or, more commonly, by ovulation induction with fertility drugs such as clomiphene citrate, human menopausal gonadotropins, gonadotropin releasing hormone, and others.

Protocols for ovulation induction vary among IVF practitioners. Development of follicles under the influence of fertility drug stimulation is usually monitored by ultrasound imagery (see figure 7-2) and blood estrogen levels. Eggs are collected by aspiration of the fluid inside the follicles via laparoscopy or nonsurgically with ultrasound-guided aspiration techniques. Once the oocytes are collected, their maturity is assessed microscopically, and fertilization of mature eggs is attempted with washed sperm. If available, at least 50,000 motile sperm per oocyte are added to the culture dish to achieve fertilization. The sperm and oocytes are incubated for about 18 hours. Oocytes are then examined to see if fertilization has occurred (evidenced by the presence of pronuclei). The fertilized oocytes then cleave, usually within 35 hours after insemination, and the resulting embryos are transferred back to the uterine cavity at the 2- to 16-cell stage (see figure 7-3). After transfer, progesterone or hCG administration may be given to supplement the natural luteal phase hormonal environment. If implantation occurs, small increases in hCG can be measured within a few days.

Figure 7-2.—Ultrasonogram of Developing Follicles



Ultrasound is routinely used to monitor the growth and development of follicles under the influence of fertility drug stimulation. The black areas represent fluid-filled follicles that contain the maturing oocyte. The size of a follicle can be estimated from sonogram.

SOURCE: IVF Program, Medical College of Virginia, Richmond, VA, 1987.

IVF treatment is indicated in a number of disorders including tubal disease unresponsive to therapy, endometriosis, cervical mucus abnormalities, oligospermia, idiopathic infertility, and any combination of these disorders. The success rate for IVF varies considerably among programs (see chs. 8 and 15).

Gamete Intrafallopian Transfer

Gamete intrafallopian transfer is an infertility treatment method that directly transfers sperm

Figure 7-3.—Multicellular Embryo

Human embryo developing in vitro before transfer to female reproductive tract or cryopreservation.

SOURCE: ©Reprinted with permission. A.A. Acosta and J.E. Garcia, "Extracorporeal Fertilization and Embryo Transfer," *Infertility: Diagnosis and Management*, J. Aiman (ed.) (New York, NY: Springer Verlag, 1984).

and oocytes into the fallopian tubes. As a consequence, fertilization can take place within the fallopian tubes. This technique relies on both medical and surgical procedures (3).

Development of follicles is accomplished by the administration of either clomiphene citrate or human menopausal gonadotropin or both. Thirty-six hours before GIFT is to take place, hCG is administered to the patient to precipitate ovulation of the mature follicles. The oocytes are collected by aspiration of the developed follicles through laparoscopy. Approximately 2.5 hours before the procedure, a semen sample is collected, prepared by washing and swim-up techniques, and treated with antibiotics. After evaluation of both the sperm and oocytes, one or two oocytes are loaded into a catheter. Next an air bubble is introduced into the catheter, followed by 100,000 motile sperm. The catheter is then threaded through the operating channel of the laparoscope into the end of the fallopian tubes for a short distance (1.5 centimeters). The contents of the catheter are gently emptied into the fallopian tube and, if possible, the procedure is repeated for the other fallopian tube. Subsequently the patient usually receives daily progesterone treatment for up to 8 weeks.

In some instances of male infertility, when small numbers of sperm are available, a variation of this procedure may be employed. Oocytes retrieved after ovulation induction may be fertilized in the laboratory as with IVF. The resulting embryo(s), however, are placed in the fallopian tubes rather than directly in the uterus.

Treatment with gamete intrafallopian transfer may be indicated in infertility related to a number of factors including endometriosis, premature ovarian failure, unexplained infertility, poor oocyte pickup by the fimbria due to adhesions, and oligospermia (3,32). Recent reports of success with GIFT are described in chapter 15.

Tubal Ovum Transfer

A less common technique with some similarities to IVF and gamete intrafallopian transfer is the tubal ovum transfer method (also known as low tubal ovum transfer). This approach uses similar ovulation induction and oocyte retrieval protocols as IVF and gamete intrafallopian transfer. However, the oocytes are transferred past a blocked or damaged section of the fallopian tube, to an area closer to the uterus. The couple then engages in intercourse or artificial insemination is performed. In this manner, the oocytes overcome the barrier created by disease or damage to the fallopian tubes and fertilization can occur within the female reproductive tract.

Embryo Lavage and Transfer

Embryo lavage (also known as ovum transfer, uterine lavage, or flushing) involves the retrieval of a fertilized ovum from the uterus by means of a specially designed catheter. After carefully monitoring a menstrual cycle to determine the point of ovulation, artificial insemination is performed on a fertile donor woman. Several days later a specially designed catheter is inserted into the female reproductive tract and the fertilized ovum is literally flushed out and retrieved. The ovum is then transferred to a waiting recipient whose cycle has been synchronized in such a way that the uterine lining is prepared for implantation (10,11).

Male Infertility

Repair of Varicocele

Varicocele is the presence of a dilated varicose vein in the testes. This condition occurs in between 10 and 20 percent of all men and approximately 20 to 40 percent of infertile men. Varicoceles are most often found in the left testis, probably because of the anatomical differences between the blood supply to left and right testes. In some cases, however, there may be a right testis varicocele (55).

The mechanism by which a varicocele depresses male fertility remains unclear but it has been suggested that the increased scrotal blood flow may raise scrotal temperature and adversely affect spermatogenesis. Regardless of the exact mechanism, repair of varicoceles can increase the quality and quantity of the ejaculate. The surgical procedure is relatively simple. Usually, under general anesthetic, a small incision is made in the groin, the spermatic cord is located, and the spermatic vein is isolated from the spermatic artery and vas deferens. The varicose spermatic vein is tied off above the varicosity, taking care not to include or damage the artery or vas deferens. Alternative approaches to this procedure include insertion of a small balloon to occlude the vein or injection of substances that will block the veins. In some cases the varicocele may reappear due to either recollateralization or failure to ligate all branches of this vein during prior surgery (55).

Improvement in semen quality after this procedure can take 3 months or longer. Reports of the effectiveness of this procedure vary widely (22,61). Of the individuals who do show improved semen analysis, a smaller percentage have partners who eventually become pregnant. Although this procedure remains one of the oldest and simplest treatments for male infertility at the moment, its efficacy for improving male fertility remains controversial.

Microsurgery

A number of other conditions contribute to infertility in the male that can be effectively treated with surgery. Only the most frequently performed procedures are discussed here. These conditions result in blockage of sperm transport through the delicate ducts of the male reproductive tract. These obstructions can arise in the epididymis, vas deferens, or ejaculatory ducts for a variety of reasons, including inadvertent damage during previous surgery or vasectomy, infections, or failure to develop as a result of a birth defect.

Reconnection or reanastomosis of the vas deferens (also known as vasovasostomy or vasectomy reversal) is a delicate operation that must be performed by a skilled microsurgeon. Portions of the vas deferens are cut away until two clean ends are obtained. To ensure that all obstruction of the duct has been removed, small samples of fluid are taken from the testicular end of the vas and examined for sperm. This procedure is continued until the presence of large numbers of sperm confirm no further occlusion between the testis and the vas deferens. The two ends are then carefully aligned and sutured together. The success of this procedure is greatly influenced by the skill of the surgeon (62).

The other location in the male reproductive tract where blockage or occlusion is likely to occur is the epididymis. Blockage here most often is a result of infection and inflammatory reaction. Because the epididymis is such an extensive duct (approximately a 20-foot-long coiled tube), pinpointing the location of the obstruction can be difficult. However, by carefully excising portions of the epididymis until sperm are observed, the occlusion can be eliminated. Once sperm are present, the end of the vas deferens is connected to the patent epididymal duct (62).

ARTIFICIAL INSEMINATION

Artificial insemination is one of the oldest forms of infertility treatment, having been performed in the nineteenth century. Even though more sophisticated infertility treatment techniques have been developed since these early reports, artificial insemination continues to be one of the simplest and most successful infertility procedures.

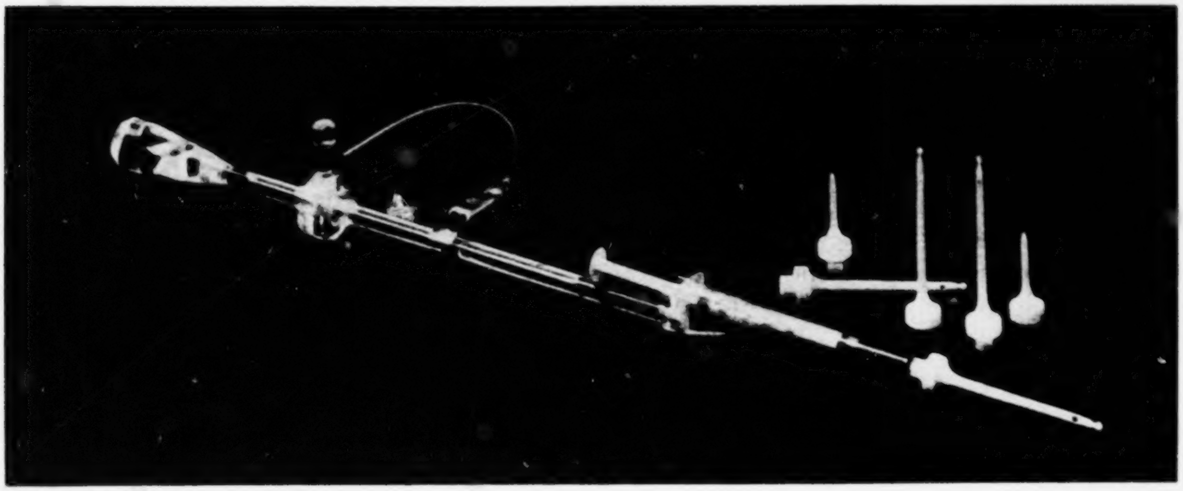
The practice of artificial insemination is usually classified as using the husband's sperm for insemination or using donor sperm. In each case the sperm can be placed either within the cervical canal or directly into the uterus. In addition, an approach that places sperm directly into the body cavity (peritoneum) has been successful in treating infertility. All inseminations are performed around the time of either drug-induced or natural ovulation.

Intracervical

Intracervical insemination involves placing sperm in or near the cervical canal of the female reproductive tract by means of a syringe or catheter (see figure 7-4). Protocols vary among practitioners but multiple inseminations during each fertile period are usually performed to increase the likelihood of conception.

The optimum time for insemination is the period just prior to or during ovulation, before basal body temperature rises. Cervical mucus is most receptive to sperm at this time. Approximately 48 hours before the expected BBT rise, sperm are collected from the husband or donor by masturbation into a clean, sterile container. In some cases, sperm are collected after the couple has had intercourse using a condom. In these instances, the condom should be void of lubricants and spermicides. The collected semen is allowed to liquefy and a semen analysis performed. Usually, within 1 to 2 hours after collection, part of the semen sample is loaded into a syringe with a flexible tip and placed in the cervix. The remaining sperm are placed in a special cervical cup that fits over the cervix. This cup remains in place for 6 to 8 hours to retain the sperm within the cervical canal and is then removed by the patient. Similar procedures are employed when frozen donor sperm are used. Intracervical insemination with the husband's sperm

Figure 7-4.—Device Used for Artificial Insemination



Artificial insemination is usually performed with a syringe similar to the device shown.

SOURCE: Zygotek Systems, Inc., Springfield, MA, 1988.

is usually indicated in cases where the male fails to deposit sperm in the female reproductive tract.

Intrauterine

Intrauterine insemination differs from intracervical by the location of sperm deposition in the female reproductive tract. In instances where cervical mucus is hostile to sperm, it is often advantageous to bypass the cervix and place sperm directly in the uterine cavity. Washed sperm are used with intrauterine insemination.

Direct Intraperitoneal Insemination

One technique for infertility treatment involves the same methods of ovarian stimulation and sperm preparation as IVF and gamete intrafallopian transfer. However, 35 hours after hCG is administered to precipitate ovulation, a sample containing at least 6 million sperm is injected directly into the body cavity between the uterus and the rectum. It appears that at least 500,000 motile sperm are needed for fertilization to occur with this method. If ultrasound shows that the follicles have not ruptured 24 hours after the first insemination, then the sperm injection is repeated. In the initial reports based on a small sample, this relatively simple technique produced a pregnancy rate of 14 percent per treatment cycle (26).

Sperm Preparation

Sperm Washing

Sperm washing is performed to separate viable sperm from the other components of the semen such as prostaglandins, antibodies, and possibly micro-organisms. This can also work to concentrate the viable sperm into a smaller volume for insemination. The basic approach involves diluting the semen sample with various tissue culture media containing albumin or serum, which somehow helps maintain sperm motility. This mixture is then centrifuged at low speed to separate out sperm (2). The concentrated sperm are resuspended in appropriate solutions for artificial insemination, IVF, or gamete intrafallopian transfer.

Swim-up Techniques

The swim-up technique is employed to concentrate only the highly motile sperm in the semen sample. This is usually accomplished by layering a solution containing proteins (albumin) or other substances over the semen or washed sperm sample. During a short time the most motile sperm in the sample will literally "swim up" into the top layer, leaving behind most of the abnormal and nonmotile sperm. Motility of the sample used for insemination can be increased severalfold, thereby increasing the likelihood of successful fertilization (2).

Drug Treatment

Disorders of motility may sometimes be improved by addition of chemicals such as caffeine, arginine, or kinins to the semen sample, but the efficacy and safety of these procedures is unclear (7). Other drug treatments of the ejaculate most notably include treatment of the sample with antibiotics to eliminate possible bacterial infection (2).

CRYOPRESERVATION

Gametes

Sperm

Spallanzani's 1776 report of sperm survival after freezing in snow was the first step to modern cryopreservation of sperm in both humans and animals (41). It was only after the discovery that glycerol, acting as a cryoprotectant, was effective in preserving sperm's survivability during freezing that successful insemination of women with previously frozen and thawed sperm was accomplished (9). Since then many laboratories have successfully frozen sperm to be used in subsequent insemination. Large-scale operations of semen collection and cryopreservation have become a major part of the animal husbandry industry. For humans, sperm banks and programs now exist around the world from which donor sperm can be purchased for insemination.

Techniques for sperm cryopreservation differ among laboratories. Most facilities now use cryoprotecting agents such as glycerol, and they freeze sperm in straws or ampoules in liquid nitrogen (41). Although some loss of sperm or sperm motility during freezing is expected, this can vary greatly depending on characteristics of original sample, freezing technique, and cryoprotectant.

Oocytes

Three births have been recorded in Australia and West Germany from oocytes that were frozen and thawed. Freezing oocytes is not widely practiced, however, in IVF programs at present. Although the technique is similar to freezing sperm and embryos, different characteristics of the unfertilized oocyte make it extremely susceptible to cryopreservation damage (71). Much additional work is needed before oocyte freezing is a viable procedure in infertility treatment.

Embryos

Cryopreservation of embryos is increasingly practiced in IVF programs around the world. This approach presents several advantages. If multiple eggs are retrieved and fertilized during an IVF cycle, then any embryos not transferred during that cycle would be available for transfer during subsequent cycles without additional fertility drug stimulation and egg retrieval. Another aspect of cryopreservation of embryos is the ability to reduce the risk of multiple pregnancies by transferring only one embryo at a time. However, this transfer protocol reduces the chances of pregnancy as well.

The techniques for freezing embryos differ in several respects among laboratories. The major differences involve the substance used to protect the embryo from damage by freezing (the cryoprotectant), and the stage at which the embryo should be frozen to ensure maximum survivability upon thawing (71). In addition, the length of time the embryos remain frozen also varies. One recent study suggests freezing embryos at the earlier, 1-cell to 4-cell stages is optimal (70,71). Conflicting reports make it unclear whether the length of time an embryo is frozen is a factor on post-thawing success (70,71).

RISKS OF INFERTILITY TREATMENTS

As in most areas of medical practice, there are potential risks associated with certain procedures used in infertility treatment. These risks can generally be divided into several categories: risks involved with drug treatments; risks associated with surgical procedures; and risks of pregnancy complications including miscarriage, ectopic pregnancy, and multiple gestations. Risks of some of the most commonly used treatments are discussed in this section.

Drug Treatments

Female

Risks related to ovulation induction with various fertility drugs have been widely investigated. Clomiphene citrate can result in subadequate cervical mucus, impaired tubal motility, abnormal sperm transport, and luteal phase defect (58). Although some reports have suggested that CC may contribute to an increased incidence of early pregnancy loss (2.5 times more likely than in spontaneously conceived gestations) (29), other reports have found no such increase (1,42).

Treatment with CC may increase the risk of ectopic pregnancy (16). This increased risk may be due to alterations in tubal motility, to a higher incidence of damaged tubes in infertile women (who tend to get placed on drugs such as CC), or to the increased number of ova released after ovulation induction, raising the number of opportunities for a tubal implantation (15).

Multiple gestation is another risk of CC and other drugs used to induce ovulation, increasing the risk of pregnancy complications including prematurity, gestational diabetes mellitus, toxemia, and placental abnormalities. The incidence of multiple gestations after CC use has been reported to range from 8 to 13 percent (58).

Other risks of CC treatment include hyperstimulation of the ovary (ovarian enlargement), moler intrauterine pregnancies, vitamin B_{12} deficiency, and possible premature aging of the ovary from repeated stimulations (38).

A number of the risks described for CC use may also be applicable to ovulation induction with human menopausal gonadotropins. As reported for CC, hMG treatment may be associated with luteal phase defect (21). Risk for ovarian hyperstimulation syndrome (OHSS) is more prominent with hMG than CC administration (20). Severe OHSS can include ovarian enlargement (which may be massive), abdominal distension, increased blood viscosity, and coagulation abnormalities, leading to thromboembolism and death (49,57). OHSS is largely the result of excessive hMG administration and can usually be avoided by careful monitoring of blood estrogen levels. OHSS appears to be associated with the administration of hCG (57); if estrogen levels become too high, therefore, hCG can be withheld.

Ectopic pregnancy rates of 2.7 percent (30) and 3.1 percent (48) have been reported in hMG-induced pregnancies, similar to the incidence with CC administration. Multiple pregnancies are more commonly encountered after hMG therapy than after CC. The incidence of twin and higher order pregnancies has been reported to range from 11 percent to 42 percent of hMG-induced gestations (58).

Other drugs used in infertility treatments carry risks of side effects as well. Many individuals taking bromocriptine for hyperprolactinemia experience side effects such as nausea, hypotension, hair loss, and headache (19). More serious complications of therapy have occasionally been reported, including pleuropulmonary fibrosis, which occurs with some regularity in patients on bromocriptine for extended periods of time, as in the treatment of Parkinsonism (58). Psychosis has been reported to have been induced by bromocriptine (69), ostensibly due to effects on central neurotransmitters. Of particular concern are reports of stroke and myocardial infarction in young, apparently healthy women on moderate doses of bromocriptine. It is believed that these complications may be due to an increase in coagulability of blood (18).

As with other drugs used to induce ovulation, gonadotropin releasing hormone carries some risks. Hyperstimulation of the ovary has been reported using Gn-RH. However, this risk appears to be less likely than with CC or hMG ovulation induction (58).

The hormone that has become most widely used in the suppression of endometriosis is danazol. Most women taking this drug experience bloating and weight gain (12). Additional possible side effects include muscle cramps, flattening of the breasts, hot flushes, oily skin, depression, acne, and hirsutism (12). Other infrequent complications that have been reported include thrombocytopenia, hepatotoxicity, hepatitis, and hepatocellular carcinoma (58).

There is no evidence that danazol therapy can cause persistent reproductive toxicity after the drug is stopped; however, inadvertent administration of danazol during pregnancy can cause masculinization of female fetuses (40).

Male

A number of different agents that are used to induce ovulation have also been used in an attempt to optimize semen quality in infertile or subfertile men. These include androgens, CC, hCG, hMG, Gn-RH, glucocorticoids, and a variety of other agents.

The rationale for giving androgens is to temporarily suppress the activity of the testes. Subsequent withdrawal of the androgens then might be accompanied by a rebound increase in spermatogenesis. Androgens administered to some men may suppress sperm production altogether with no subsequent rebound. It is unclear, however, if this is a complication of the drug treatment or of the primary testicular disorder for which the therapy was given (58).

The use of CC in oligospermic men is based on the anti-estrogenic activity of this drug. There have been occasional reports of serious adverse effects of this therapy, including a case of pulmonary embolism (13) and two cases of testicular germ cell tumors after therapy (51). The occurrence of such isolated cases may be coincidental and cannot be interpreted as indicating a risk of the therapy. It is considered unlikely that CC poses a significant health risk for men (58).

Glucocorticoids have been used in men to reduce the development or activity of sperm antibodies. Glucocorticoids, given chronically, may be associated with adrenal suppression, osteoporosis, impaired glucose tolerance, psychosis, and other complications. Men receiving glucocorticoids for sperm antibodies develop such complications as readily as any other patient (54).

Side effects and potential complications of bromocriptine, used to treat male infertility, are similar for men and women.

Surgery

Female

The complications of general anesthesia, including drug reactions, cardiac depression, hypotension, aspiration, and death, do not appear to be different for infertility surgery than for surgery in general. Surgical complications such as injury to bowel, excessive blood loss, and infection are possible with any intra-abdominal operation (58).

Because surgery may cause scar tissue of its own, much effort has gone into developing procedures to prevent postoperative pelvic adhesions. However, adhesions and scarring remain potential consequences of reproductive tract surgery.

The complication of tubal surgery of greatest concern is ectopic pregnancy. A number of investigators have reported ectopic pregnancy rates after tubal surgery ranging from 4 to 38 percent (58).

Use of lasers at laparotomy for tubal reconstructive surgery may be associated with complications specific to the laser, such as inadvertent reflection of the laser beam resulting in damage to other tissues or in the starting of fires in the surgical drapes. The incidence of documented injury from laser surgery in the abdomen has been reported to be less than 0.5 percent (18).

Laser laparoscopy is an acceptably safe tool for the treatment of endometriosis, although intra-abdominal bleeding may require the use of traditional cautery for control. Based on the limited number of reports available, serious complications do not appear to occur more often than in laparoscopies in general (58).

Male

The major risk of male genital tract surgery such as reversal of vasectomy is operative infection and bleeding. The major complication of varicocele ligation is postoperative hydrocele, a collection of fluid in the scrotum. The fluid collection may be due to inadvertent destruction of lymphatic drainage vessels during the procedure (68).

Testicular atrophy was also at one time a complication of varicocele ligation, occurring in as many as 14 percent of cases. Improvements in surgical technique appear to have eliminated this complication (28).

Artificial Insemination

The major risk of artificial insemination by donor is transmission of disease from the donor to the recipient, including chlamydia, gonorrhea, cytomegalovirus (a potential cause of fetal illness), hepatitis B virus, and human immunodeficiency virus (38,58). The risk appears to be less after intracervical insemination than after intrauterine insemination (67).

In Vitro Fertilization

IVF can involve a number of procedures that each have risks and possible complications. Ovulation induction for IVF often involves several fertility drugs (CC, hMG, Gn-RH, hCG) used in combination and carries the risks described previously.

Many IVF cycles demonstrate features of luteal phase deficiency (8,27). It has been proposed that aspiration of the follicle to obtain the ovum may damage the follicle or may remove too many granulosa cells, which impairs subsequent luteal phase function. Experience with human IVF cycles suggests that the agents used to hyperstimulate the ovary are more likely than aspiration to be responsible for luteal dysfunction (74).

Several oocyte retrieval methods employing ultrasound-guided aspiration have been developed (44). Since the aspirating needle may traverse the bladder, blood in urine is seen with regularity after this procedure (38,58). It is likely that ultrasound-guided aspiration of follicles will replace laparoscopy in many programs due to comparable results and lower cost, fewer discomforts, and less risk with the nonoperative approach (34).

Obtaining multiple oocytes leads to the possibility that more embryos will be generated than can be transferred in a given IVF cycle. The cryopreservation of excess embryos for use in future cycles is being considered an important option in more and more programs. Thawing of frozen embryos often fails to yield viable embryos. Long-term effects to individuals born after embryo cryopreservation remain to be fully investigated.

As the number of embryos transferred per cycle increases, so does the incidence of multiple gestations. Several complications attributable to the embryo transfer procedure have been reported. The catheter used to introduce the embryos into the uterus may result in trauma to the endometrium (50). The transferred embryos may implant in the fallopian tube. The first IVF pregnancy was, in fact, a tubal pregnancy (65). Some programs report an ectopic pregnancy rate of 2 to 3 percent (39); however, a review of the experience of a number of programs reported that 10 percent of IVF pregnancies are extrauterine (6). The placement of the catheter high in the uterus may predispose to ectopic pregnancies. One study reported a 17-percent ectopic rate with high placement as opposed to a 2-percent ectopic rate when the catheter was place in the middle of the cavity (77).

The miscarriage rate for infertility patients is generally higher than that for the normal population. Although rates as high as one in three have been reported for some infertility patients, determination of these risks remains a complex undertaking (see ch. 15).

Preterm delivery is more common in pregnancies after IVF than in spontaneous pregnancies (4,43). This is partly due to the high incidence of multiple gestations, although an increased prematurity rate is also seen in births of one infant.

KNOWING WHEN TO STOP

> When you absolutely cannot have children, it's called sterility. When it seems to be taking an awfully long time but you still hope, it's called infertility.
>
> Infertility is worse.
>
> Katherine Bouton
> *Ms.*, April 1987

Current estimates indicate that even appropriate therapy will assist only 50 percent of infertile couples to achieve a pregnancy. Couples often ask how to know when to quit trying medical treatments. Their uncertainty is complicated by prevalent social assumptions that anything is possible if one works hard enough, that "where there is a will there is a way." In addition, the lack of information about idiopathic infertility in particular contributes to the fear of stopping too soon and perhaps omitting what would have been a successful treatment.

Medical indications for stopping treatment are not yet well developed because:

- selected reproductive technologies have only recently proliferated and instances of overuse have not been well documented;
- the current high costs of diagnosing and treating infertility cause many couples to exhaust their personal resources well before they have exhausted available treatments; and
- existing services for infertile couples may not help the couple to know when the stress associated with continued diagnosis and treatment is excessive.

Infertile couples who can afford to continue treatment may assume that infertility specialists will tell them when to stop, but in their desire to help infertile couples to conceive, physicians may not often enough pause to consider if a particular couple should stop trying.

It may be helpful for infertile couples to ask themselves:

- Is further treatment worth the pain, expense, and disruption?
- Is adoption or childfree living becoming an acceptable option?
- Is treatment costing so much that other goals are sacrificed?

- If it is not yet time to stop, when will it be?

New information about infertility and overuse of certain reproductive technologies may help to make this decision, but knowing when to stop will continue to be an individual matter for every infertile person and couple.

SUMMARY AND CONCLUSIONS

A variety of traditional and more recently developed medical and surgical treatments for infertility exist. Treatments often involve both members of a couple, each of whom may have a condition that causes subfertility. Medical treatment can range from instruction of the couple in the relatively simple methods of pinpointing ovulation to more complex treatments involving ovulation induction with fertility drugs followed by artificial insemination. Surgical treatments also span a wide spectrum of complexity, from ligation of testicular veins for varicocele repair to delicate microsurgical repair of reproductive tract structures in males and females.

As is true for the diagnostic procedures described in chapter 6, far fewer procedures exist for the treatment of male infertility than for female infertility. This underscores the lack of basic knowledge about male reproductive physiology and the paucity of approaches to treat dysfunctions of this system.

Although sophisticated noncoital reproductive technologies such as IVF or gamete intrafallopian transfer offer some hope to some infertile couples who could not otherwise be successfully treated, improvements of more traditional infertility treatments such as ovulation induction, traditional surgery and microsurgery, and artificial insemination continue to make these treatments the most widespread and successful approaches. It is also important to note that even complex and sophisticated treatment of one partner will be of no benefit if the other partner suffers from undiagnosed infertility. Therefore, as with diagnostic technologies, the couple as a unit is properly considered as the infertility patient.

Even as infertility treatments become more sophisticated and complex, basic knowledge of the male and female reproductive process remains lacking. Further research stands as a prerequisite in order for dramatic improvements in infertility treatment to occur.

CHAPTER 7 REFERENCES

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Chapter 8

Infertility Services and Costs

This chapter examines the current state of infertility-related services from the perspectives of costs, affordability, and insurance coverage. For the purposes of this report, infertility-related services, referred to as infertility treatment, include medical and surgical diagnostics and treatments that attempt to directly overcome diseases and disorders that cause infertility as well as technological procedures and practices that attempt to circumvent infertility conditions.

As infertility-related services are adapted and refined, and as infertility treatment centers increase in number, questions arise about the costs of the services, the recipients of treatment, and the effectiveness of the services. This chapter considers:

- How much do various infertility treatments and technologies cost for typical courses of treatment? For atypical treatments?
- What are the total infertility-treatment-related expenditures in the United States? How is the infertility health care dollar spent? How is the cost burden distributed among individual, public, and private payers?
- How effective are different infertility treatments? Do certain types of infertility treatments have better success records than others and, if so, are these success rates correlated with identifiable factors?
- How widespread is access to infertility treatment for various types of infertile couples? Does access depend on income, geographic location, or other factors?

The number of new infertility cases per year is unknown, but has been estimated to be between 111,200 and 161,240 (6,7). The number of patients receiving treatment for infertility is estimated at between 200,000 and 300,000 per year, for the following disorders:

- ovulatory disorders, 120,000 patients;
- endometriosis, 30,000 patients;
- tubal disorders, 20,000 to 40,000 patients; and
- seminal factors, 20,000 to 45,000 patients.

In addition to these estimates, the National Survey of Family Growth estimates that about 1 million couples use some form of infertility services annually (15,18).

INFERTILITY TREATMENT SCENARIOS

In most cases, infertile couples first seek medical assistance so that they can have a baby genetically related to each of them. Should these attempts fail, they may consider methods by which they can have a baby that is the genetic product of at least one member of the couple (i.e., artificial insemination by donor, embryo donation, ovum donation, or surrogate motherhood), or they may consider adoption. In comparing the costs and availability of assistance for infertile couples, it is important to keep in mind the widening range of alternatives that infertile couples face.

This discussion focuses on infertile married couples, primarily on the women. Although men and women are equally likely to be infertile, male infertility does not account for an equal proportion of the costs spent on infertility because there are relatively few diagnostic and treatment services for men.

In treating infertility, the more tailored the protocol is to the patient, the more likely the chance of success. Some specialists, for example, treat endometriosis with surgery, with drugs, or with both; the choice of therapy, the length of time, and the drug dosage prescribed depends on the woman's history and reactions as well as on the severity of the disease. Many patient-specific decisions may be made over the course of treatment; the results of each test and the success of each treatment indicate the next steps to be taken. Because of the varieties of sources and types of infertility, it is often difficult to determine whether standard treatment protocols exist, how much each treatment costs, and what the effectiveness is expected to be.

In addition, as in any advancing medical arena, infertility specialists disagree as to the proper course of action in many cases. Some physicians investigate mechanical problems such as blocked or scarred fallopian tubes as part of the routine workup; others wait until ovulatory problems are cleared up before determining the status of the tubes (4).

Finally, there are trade-offs to be made in cost, convenience, and surgical invasiveness. For example, most infertility workups do not routinely include a sperm penetration (hamster-oocyte) test because of its $300 price tag and the uncertainty of its importance. Nevertheless, hindsight can sometimes show that the test would have been appropriate and would have saved thousands of dollars and numerous invasive procedures.

More often, cost savings can be gained by grouping procedures together. For example, if a hysteroscopy, hysterosalpingogram, and laparoscopy are all performed at the same time, the cost to the patient will likely be lower than if the hysterosalpingogram is done earlier, in an outpatient setting. Furthermore, an early hysterosalpingogram may indicate no need to proceed with surgical diagnostics. Practices vary among specialists.

To examine the typical costs and procedures faced by an infertile couple, a series of hypothetical scenarios were developed to reflect the course of diagnosis and treatment of common infertility problems (4,12). The scenarios proceed from simple procedures to more complex techniques. A detailed description of the types and cost of possible procedures involved is presented in table 8-1. Table 8-2 summarizes the procedures and costs for each scenario.

Stage I Scenario—*Initial Diagnosis and Treatment*. Couple seeks treatment for infertility. Full patient histories and physicals are performed; routine tests are done to check hormone levels and sperm quantity and motility. Counseling may be offered to determine whether behavioral changes may be helpful and to inform the couple of options and prognoses.

Assume, for purposes of the scenario, that the problem is oligomenorrhea (scanty or infrequent menstruation), a problem found in about 20 percent of infertile women and roughly applicable to women suffering ovulatory problems in general. The treatment prescribed in this stylized version of infertility services is the use of fertility drugs, first with clomiphene citrate, then (assuming that clomiphene citrate is ineffective) with menotropins (human menopausal gonadotropins).

Stage I diagnosis and treatment is estimated to require about 6 to 9 months to complete, yielding a pregnancy rate of about 30 percent. Thus, if 100 infertile women were to begin this course of treatment, 30 pregnancies would be expected at the end of Stage I. Total costs of Stage I for the couple are $3,668.

Stage II Scenario—*Comprehensive Infertility Evaluation for Persistent Infertility*. This scenario includes the full range of diagnostic tests for nonovulatory causes of infertility, including investigation of infections, hysteroscopy, and cervical mucus tests. Some of the tests may have therapeutic value as well, and thus represent both diagnostic and treatment services. This is especially true for laparoscopy; where feasible and necessary, surgery for endometriosis or adhesions can be performed at the same time a diagnostic laparoscopy is done.

Stage II is likely to require about 1 year to complete, although for many couples less time is required for a diagnosis. This more comprehensive evaluation is likely to pinpoint fertility problems that are less obvious than oligomenorrhea, such as endometriosis, adhesions, sperm antibodies, luteal phase defects, and others. Once diagnosed, these conditions would receive appropriate treatments. It is estimated that Stage II would have a 30-percent success rate, and would cost $2,055. If the 70 couples who did not conceive after Stage I continued on to Stage II, at the end of 18 to 21 months (end of Stage II), out of the original 100 infertile women, there would be a total of 51 pregnancies (i.e., 30 plus 0.3 times 70) . The total cost of only diagnostics from both Stages I and II is $2,905 (7,11).

Stage III Scenario—*Tubal Surgery*. The assumption in the Stage III Scenario is that the Stage

Table 8-1.—Estimated Costs of Infertility Services, 1986[a]

Service	Median survey cost	Survey range of costs	Other estimates
Diagnostic services:			
Patient history and full physical	$120	$50-415	$ 60[b]
Infection screen	$ 40	$18-138	
Sonography (per exam)	$100	$40-186	
Hormone tests (per test)	$ 50	$25-85	
Pelvic exam	$ 40	$18-75	$ 40[c]
Cervical mucus:			
Postcoital test	$ 40	$25-100	$ 25[b]
Mucus penetration	$ 40	$25-200	
Hysterosalpingogram	$150	$50-1,500	$100-300[c] $150[b]
Endometrial biopsy	$ 85	$50-350	$100-300[c] $100[b]
Hysteroscopy	$400	$130-1,100	
Laparoscopy	$800	$400-2,500	$650-900[c] [d]
Semen analysis	$ 45	$15-108	$25-70,[c] $15[b]
Sperm antibody test	$ 75	$35-300	$300[c]
Hamster-oocyte test	$275	$35-390	$300[c]
Infertility counseling	$ 75[e]	$38-135	
Treatment services:			
Medical treatment:[f]			
Clomiphene citrate	$ 30 per month	$16-75	$20/month[b] [c]
HMG	$ 28 per ampule	$24-38	$40-42[b] [c]
	$588 per month	$200-1,500	$420-504[c]
HCG	$20 per 5,000 units	$10-45	
Danazol	$160 per month	$120-200	$120,[g] $135[b]
Bromocriptine	$ 90 per Rx	$30-450	
Tubal reversals	$2,500[h]	$1,300-5,000	
Reversal of vasectomies	$2,000[h]	$1,000-2,500	
Tubal surgery for PID	$2,000[h]	$750-3,800	$3,000-6,000[c]
Repair of varicocele	N/A	N/A	$2,000-2,500[c]
Laser laparoscopy	$1,200	$485-3,000	
Endometriosis-ablation	$1,200	$400-5,000	
In vitro fertilization	$4,688	$775-6,200	$4,000-6,000[c]
Frozen embryo transfer	$500	$220-1,800	
Gamete intrafallopian transfer (GIFT)	$3,500	$2,500-6,000	
Artificial insemination			
Husband's sperm			$35-90[c]
intracervical	$ 53	$30-105	
intrauterine, washed sperm	$ 85	$40-200	
Donor sperm			$35-90,[c] $25[b]
fresh	$ 80	$35-150	
frozen	$100	$40-350	
donor fee			$50-100[c]

[a] Median costs reported by IVF centers contacted in a November 1986 OTA survey. Figures reported are generally on a per test or per procedure basis, for the first in a series, where a series is applicable. For example, one form of artificial insemination is reported at a median cost of $53. Typically, the $53 would reflect the initial artificial insemination; subsequent attempts (up to, say, three times per month for 6 months) might be lower in cost. Similarly, only the cost per hormone test is given, although a battery of tests is usually done. Examples of actual costs to patients for a given protocol are provided in the scenarios developed in the next section.

[b] G. Cooper, "The Magnitude and Consequences of Infertility in the United States," prepared for Resolve, Inc. February 1985, and G. Cooper, "An Analysis of the Costs of Infertility Treatments," *American Journal of Public Health* 76:1018-1019, 1986.

[c] D. Harris, "What it Costs to Fight Infertility," *Money*, December 1984.

[d] Hospital laparoscopy runs between $1,650 and $1,900 (c), or around $1,500 (b).

[e] Counseling charges are often included in charges for full history and physical.

[f] Drug charges only; excludes physician charges.

[g] J.H. Bellina and J. Wilson, *You Can Have a Baby* (New York, NY: Crown Publishers, Inc., 1985).

[h] Physician fees only; excludes hospital charges. Cooper, 1985 (b), estimates $3,500 for all surgical procedures.

SOURCE: Office of Technology Assessment, 1988.

Table 8-2.—Scenarios of Infertility Diagnosis and Treatment

Infertility service		Cost
Stage I Scenario—Oligomenorrhea		
Diagnostics		
Patient history and physical	$120×2	$ 240
Hormone tests	$50 per test, battery of 3 run 3× in 1 month	$ 450
Pelvic exam		$ 40
Semen analysis		$ 45
Counseling		$ 75
	Total:	$ 850
Fertility Drug Treatment		
Clomiphene citrate		
Drug costs	5 days per month	$ 30
Blood tests	$40×3	$ 120
Ultrasound		$ 100
Physician visits	$40×2	$ 80
	Total	$ 330
	×4 months	$1,330
HMG (1 month)		
Drug costs, 5-10 days	$28 per ampule×3 per day×7 days	$ 588
Blood test run each day		$ 350
Ultrasound		$ 250
HCG		$ 20
Physician visits	$40×7	$ 280
	Total	$1,488
	Drug treatment total	$2,818
	Total, Stage I Scenario (6-9 months)	$3,668
Stage II Scenario—Complete Infertility Evaluation		
Screening for infections		$ 40
Sonography		$ 100
Cervical mucus		$ 80
Endometrial biopsy		$ 85
Hysterosalpingogram		$ 150
Hysteroscopy		$ 400
Laparoscopy (outpatient) (including laser)		$1,200
	Total, Stage II Scenario (12 months)	$2,055
Stage III Scenario—Tubal Surgery		
Tubal surgery (for PID)		
Physician costs		$2,000
Hospital charges (anesthesia, operating room, hospital stay)		$1,500
Laparoscopy		$ 800
Fertility drug treatment (see Stage I Scenario)		$2,818
	Total, Stage III Scenario (18 months)	$7,118
Stage IV Scenario—In Vitro Fertilization		
History and physical, counseling		$ 150
Drugs (chemical stimulation) Clomiphene citrate HMG HCG		$ 638
Ultrasound assessment of follicular growth		$ 500
Hormone blood tests		$ 425
Laparoscopy Physician fees Anesthesia Operating Room		$1,500
Embryology and embryo transfer Laboratory Physician		$1,100
Hospital room		$ 250
Followup, routine tests		$ 125
		$4,688
	x 2.0 cycles	
	Total, Stage IV Scenario (6 months)	$9,376

SOURCE: Office of Technology Assessment, 1988.

II evaluation indicates blocked or damaged tubes. Tubal surgery is then performed on the woman to repair or open blocked or damaged tubes. In the absence of pregnancy following surgery, another laparoscopy may be done and fertility drug treatment may be started again.

Stage III is estimated to last about 18 months and to result in a 30-percent pregnancy rate. If the 49 couples who had not conceived after Stage II had all proceeded to Stage III, about 15 would become pregnant, bringing the total of pregnancies to 66. Total cost of the Stage III scenario is estimated at $7,118. Total cost for all three scenarios is $12,841.

Stage IV Scenario—*In Vitro Fertilization (IVF).* When pregnancy does not result after tubal surgery, IVF may be considered. Only one-third to one-half of the women who make it to this stage are likely to be suited to IVF. If one-third of the remaining 34 couples undertake IVF, and assuming a pregnancy rate in expert hands of 25 percent for IVF, an additional three pregnancies would result among the 11 couples. Total cost of Stage IV, assuming an average of two IVF cycles per couple, is estimated at $9,376 over 6 months. This estimate assumes retrieval of eggs is done by laparoscopy rather than with ultrasound, and that embryos are not frozen. Total cost for a couple undergoing all four stages is $22,217.

All four scenarios thus yield a total of 69 pregnancies out of 100 original infertile women. With a 25-percent miscarriage rate, the number of women having successfully completed pregnancies resulting from these scenarios would be about 50.

Although these scenarios are a hypothetical version of the individualized treatment actually offered to patients, they represent most of the procedures commonly used in infertility treatment. Table 8-3 summarizes the scenarios, the associated investments of cost and time, and the resulting expected pregnancy rates.

Significant changes even in these stylized scenarios can be expected over the next several years as technological advances occur. Some of these developments are foreseeable, and some are already being applied in a few centers but have not yet taken hold industry-wide. Embryo freezing, for example, allows IVF to be tried a second, and possibly a third, time without requiring additional ovulation induction and oocyte-retrieval. As embryo freezing develops and becomes more successful, the costs of subsequent treatment cycles could drop by half. In addition, ultrasound rather than laparoscopy is gaining wider use for oocyte retrieval, potentially cutting costs by an additional 30 percent. The diffusion of new technology will take time, however. For example, IVF centers that have invested in developing skills and purchasing equipment used in laparoscopic surgery will not necessarily dispense with that procedure in favor of ultrasound retrieval of eggs.

The most significant change likely to occur may be the frequency with which tubal surgery is

Table 8-3.—Summary of Infertility Diagnosis and Treatment Scenarios

Scenario	Time	Cost	Pregnancy rate	Number of pregnancies
100 couples begin (after 12 months of unprotected intercourse)				
Stage I—Simple diagnosis and treatment of oligomenorrhea	6-9 months	$ 3,668	30%	30
70 couples continue				
Stage II—Complete infertility evaluation	12 months	$ 2,055	30%	21
49 couples continue				
Stage III—Tubal surgery	18 months	$ 7,118	30%	15
One-third of remaining 34 couples (11) are suited to continue				
Stage IV—In vitro fertilization	6 months	$ 9,376	25%	3
Total	at least 4.5 years	$22,217	69%	69

SOURCE: Office of Technology Assessment, 1988 bypassed in favor of IVF, gamete intrafallopian transfer (GIFT), or for a similar type of technology. To date, in most cases, IVF has been considered a last resort treatment, turned to after tubal surgery has been performed with unsuccessful results or for idiopathic infertility. There are, however, growing indications that IVF is now considered earlier on in the process—in effect collapsing Stages III and IV into a single stage. For example, should oocyte cryopreservation techniques improve, it may be routine to collect oocytes during diagnostic laparoscopies and store them for possible IVF or GIFT procedures at a later time. This approach further reduces both the cost of infertility treatment and the time involved, which is often of critical importance to couples nearing the end of their childbearing years.

COSTS AND EFFECTIVENESS OF INFERTILITY SERVICES

Data included in this section were collected by OTA from IVF/infertility centers, published infertility cost information, and other sources.

Costs

Diagnostic and treatment procedures tend to be slightly more expensive at nonprofit centers. This is most obvious for IVF, where charges may be $1,000 greater than at for-profit centers. However, this may reflect the relatively more difficult cases that are treated by larger, longer-established, nonprofit IVF centers, or merely higher fees (some of which may support IVF research projects).

The median charges reported to OTA by infertility centers surveyed (see table 8-1) may or may not reflect typical charges for procedures commonly provided by individual gynecologists and urologists who are not infertility specialists or are not associated with an IVF program. (Other data sources, giving figures generally in the same range, are also noted on table 8-1.)

In interpreting the cost data in table 8-1, it is important to recognize that infertility treatment includes an ever-widening array of approaches. The experience of the medical community with regard to proper use and resulting success of this array are far from universal. Although about 20 to 30 of these procedures are commonly used by most infertility specialists, differences exist in methods of application, timing, and experience. These differences are reflected in both costs and pregnancy rates. Thus, on some of the procedures a wide range of costs are reported, and medians are used rather than means.

Affordability

A couple proceeding through the four scenarios outlined earlier do not move automatically through each stage. Even at this highly stylized level of analysis, the process is dynamic. At each stage, some couples are successful in achieving pregnancy, while others are unsuccessful and continue on. Still other couples are unsuccessful and drop out, whether for reasons of cost and affordability, the strain on relationships and careers, advancing age, the attractiveness of other options such as adoption or surrogate motherhood, or another reason. As the couple proceeds through these stages of treatment, the chances of pregnancy recede, and the costs escalate.

To what extent are these costs affordable, both for infertile couples and for society? On an individual level, the substantial costs of the four scenarios are beyond the reach of low-income couples and represent a sizable investment for middle-income couples. Table 8-4 provides the basis for assessing the affordability of each scenario for married couples in the United States. For married couples with before-tax incomes under $20,000, the out-of-pocket costs per stage range from 6 to 62 percent of annual income. For married couples with before-tax incomes ranging from $20,000 to $35,000, infertility expenditures represent between 2 and 23 percent of annual income. Finally, for the remaining married couples, those with incomes over $35,000, costs represent between 1 and 12 percent of annual income. Alternative assumptions about the levels of income and insurance coverage of typical infertile couples would alter the results. These figures apply only

Table 8-4.—Affordability Analysis for Insured Couples

Scenario		Percent of annual household income		
		Low-income	Middle-income	High-income
Stage I:		11	4	2
Diagnosis and fertility drug treatment				
Total Cost:	$3,668			
Cost to Couple:	$1,100			
Stage II:		6	2	1
Complete Evaluation				
Total Cost:	$2,055			
Cost to Couple:	$ 617			
Stage III:		21	8	4
Tubal Surgery				
Total Cost:	$7,118			
Cost to Couple:	$2,135			
Stage IV:		62	23	12
In Vitro Fertilization				
Total Cost:	$9,376			
Cost to Couple:	$6,188			

Assumptions:

Income profiles of infertile married couples:

• Low-income group	Median income: $10,000	Range: $0-19,999
• Middle-income group	Median income: $27,500	Range: $20,000-34,999
• High-income group	Median income: $50,000	Range: $35,000 plus

—Insurance coverage:

- Assume all couples have health insurance coverage.
- Assume two-thirds to three-quarters of non-IVF infertility expenditures are reimbursed (i.e., costs to couples = 70 percent of total costs).
- Assume 66 percent of IVF costs are covered, at rate of 66 percent (i.e., 44 percent of IVF charges are covered by insurance).

SOURCE: Office of Technology Assessment, 1988.

to couples who have health insurance. They underestimate the burden of infertility costs on low- to middle-income couples, many of whom remain uninsured or underinsured.

Are the costs of pregnancies using the current range of infertility treatment services more than society is willing to pay? A recent analysis shows that such costs are roughly in line with average costs of adoption ($3,000 to $10,000) and of surrogacy ($20,000 to $45,000) (21).

Access to Services

In general, a higher proportion of white women (15 percent) than black women (10 percent) report using infertility services, particularly for women over age 24. Women who had ever been married, who had higher incomes, and who had higher educational levels reported greater use of infertility services than women never married or with low incomes or low levels of education (15,17). Women with primary infertility tend to seek services more than women with secondary infertility (13).

There is evidence that, at least in the 1976-82 period, infertility services were not reaching a considerable number of infertile couples. For example, as of 1982, about 200,000 married women with primary infertility had never sought infertility services although they wanted a baby (13). Another 550,000 married women with secondary infertility had never sought services. This latter group of women, compared with those who have sought services, tended to be of lower socioeconomic status, to have less education, and to never have worked (13,18).

With regard to financial barriers to treatment, among the private physicians surveyed by the Alan Guttmacher Institute (AGI) (1), 21 percent reported that they accept Medicaid patients; only 6 percent varied their fees for low-income patients. Among 19 specialized infertility centers, AGI reported that about half accept Medicaid reimbursement and 16 percent reduce their fees for low-income patients. The AGI study concluded that in general, people with adequate financial resources, either their own or insurance with infertility coverage, have no more difficulty obtaining infertility services than they do most other types of medical care. However, infertility services are less available to low-income couples, and low-income women face serious financial obstacles to obtaining specialized or complex infertility services.

Effectiveness

Interpreting effectiveness data in the field of infertility treatment is difficult and controversial. First, and most basically, it can be hard to determine what particular service may have been responsible for a pregnancy. Infertile couples seeking treatments are often told that their chances of success are about 50 percent. Various studies report that 21 to 62 percent of pregnancies of treated and untreated infertile couples appeared to be independent of treatment (5). An in-depth followup study of 1,145 infertile couples found that 41 percent of treated couples had pregnancies, while 35 percent of untreated couples became pregnant (5). One IVF clinic, for example, reported that five women became pregnant while on the waiting list for IVF. When a number of infertility approaches have been used over a relatively short period, it becomes virtually impossible to isolate the procedure that worked, if indeed any procedures were responsible for a subsequent pregnancy.

Effectiveness or success rate data for more traditional infertility treatments have not been as controversial as those for IVF and related approaches, in part, perhaps, because the traditional treatments have not been as closely scrutinized. Alternatively, greater emphasis on success rate and effectiveness data for IVF and related procedures may stem from the current lack of third-party reimbursement for them and the need to establish the procedures as acceptable, nonexperimental medical treatments. Rapid introduction and dissemination of these technologies may also be a contributing factor.

In evaluating the likely success of any particular procedure, there are difficulties in using most effectiveness measures (see chs. 9 and 15). One that is used is numbers of babies, but that figure may include multiple births, which do not reflect, in a sense, the desired outcome of a baby for each couple seeking one. Another measure commonly used is numbers of pregnancies, but definitions of pregnancy vary. A pregnancy may be defined as clinical, preclinical, chemical, viable, or live birth. Some IVF programs report pregnancy rates per patient, per treatment cycle, per laparoscopy, or per embryo transfer (19).

Neither babies born nor pregnancies achieved represent a full measure of effectiveness of infertility treatment. The object of infertility treatment is a safe pregnancy resulting in the live birth of a healthy baby. To the extent that certain infertility services result in increased health risks, either to the woman or to the baby, these risks diminish the "effectiveness" of the procedure. IVF pregnancies, for example, are about two to four times as likely as normal conception to result in an ectopic pregnancy (8,14,21). Other risks include the daily intake of hormones, anesthesia during egg retrieval, stress to the uterus, spontaneous abortion, and multiple pregnancies.

Finally, interpreting success rates on a center-by-center basis is difficult. Some IVF/infertility clinics are research centers; others offer only IVF, in a standard, almost production-line approach. IVF clinics associated with university medical schools and hospitals tend to receive the most difficult cases and claim that their success rates would be higher if they had a group of patients with infertility problems of varying severity. Overall, however, it is worth noting that technologies and experience take substantial time to diffuse industry-wide.

AGGREGATE U.S. EXPENDITURES

Non-IVF Expenditures

Estimates of the total cost of treating infertility in the United States allow measurement of the amount of societal resources currently devoted to this problem. One report concluded that most couples spend little or nothing for infertility problems although a few spend an extraordinary amount. As a rough estimate the report assumes an average expenditure of $200 per couple who seek help, yielding a total of $200 million for 1982. Even if the correct figure were twice as high, the overall estimate for reproduction-related health expenditures would increase by only 1 percent (9).

Another estimate placed aggregate infertility expenditures between $340 million and $460 million in 1984, based on a survey of service prices and a construction of the cost of a typical set of infertility treatment procedures (6,7). The cost of each scenario was then multiplied by an estimate of the number of people who used the service, as derived from several sources.

Data derived from an analysis of a national population-based survey, the National Medical Care Utilization and Expenditure Survey (NMCUES), and from the International Classification of Diseases Code yield an estimate of U.S. expenditures of between $345 million and $676 million, with $480 million as the intermediate estimate (21).[1]

Using the intermediate estimate, table 8-5 reports this sum by type of medical service and source of payment. Table 8-6 breaks down this figure into percentage terms of how these expenditures were distributed by type of service and source of payment. Hospital expenditures, for example, amounted to $297 million, representing 62 percent of total infertility expenditures. The other major category of services was expenditures on doctors, accounting for $151 million in 1980, or 31 percent of total infertility expenditures. Close to half that amount ($70 million) was spent on doctors' charges of over $300 per visit.

Table 8-6 also shows how a couple's dollar spent on infertility was divided among services. For every household dollar spent on infertility in 1980, more than half (55 percent) went for physician services. Over a third (36 percent) went to hospitals (mostly for inpatient services), and less than 9 percent was spent on drugs (see figure 8-1).

The picture for expenditures by private insurance companies complements that for households. Private insurers spent 69 percent of their budget on hospital care and 26 percent on physician care. Two-thirds of the expenditures on physicians were for services that cost more than $300.

The category of "all other sources" includes the amounts paid for infertility services by various government programs, philanthropy, and company clinics. Whereas these payment sources play a considerable role in national health care expenditures, they account for less than 10 percent of infertility expenditures, with nearly three-quarters of that amount spent on services provided in hospital outpatient facilities. As indicated in a survey

Table 8-5.—Infertility Expenditures in 1980, by Source of Payment (in millions)[a]

Type of service	Total charges	Households	Private insurance	All other sources
Hospital	$296.9	$ 36.7	$232.8	$27.4
• Emergency room	1.6	0.6	1.0	0.0
• Outpatient	65.0	5.4	39.9	27.4
• Inpatient	230.3	30.7	191.9	0.0
Physician service cost	150.6	56.7	87.3	6.6
• $0-100	43.0	27.3	12.4	3.3
• $101-300	37.1	20.1	16.7	0.3
• $301+	70.5	9.3	58.2	3.0
Other professional	2.6	0.3	1.2	1.1
Drugs	25.5	8.8	15.6	1.1
Other	4.0	0.4	1.5	2.1
Total	$479.6	$102.9	$338.4	$38.3

[a] For persons aged 15 to 44; estimates exclude health care expenditures by the institutional and noncivilian populations and all expenditures for nonprescription drugs.

SOURCE: Office of Technology Assessment, 1988.

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[1] This analysis employed a version of NMCUES made available by the National Institute on Aging and software developed at ICF Incorporated. The authors identified diseases related to infertility and the expenditures for those conditions. To estimate the percentage of expenditures on each disease that can be considered infertility-related, they consulted several additional infertility specialists (4,12) who provided estimates of the percentage of treatments where concern for infertility was a primary factor in determining treatment, or where it was extremely to quite likely that a patient with the disease would be treated for infertility. They then applied these percentages to NMCUES data on expenditures for each disease.

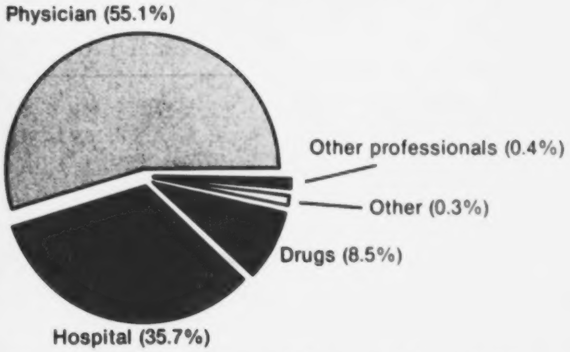
Table 8-6.—Infertility Expenditures in 1980, by Type of Service (in percentages)[a]

Type of service	Total charges	Households	Private insurance	All other sources
Hospital	62.0	35.7	68.8	71.5
Physician	31.4	55.1	25.8	17.2
Other professional	0.5	0.3	0.4	2.9
Drug	5.3	8.5	4.6	2.9
Other health	0.8	0.4	0.4	5.5
Total	100.0	100.0	100.0	100.0

[a] For persons aged 15 to 44; estimates exclude health care expenditures by the institutional and noncivilian populations and all expenditures for nonprescription drugs.

SOURCE: Office of Technology Assessment, 1988.

Figure 8-1.—Infertility Health Care Dollar: Household Expenditures



How the infertility health care dollar spent by households was divided among professionals, hospitals, drugs, and other services in 1980. Developed from National Medical Care Utilization and Expenditure Survey.

SOURCE: Office of Technology Assessment, 1988.

of private physicians conducted by the Alan Guttmacher Institute (1), the primary sources of funds in infertility treatment are patient fees and private insurance.

IVF Expenditures

Data about the cost and number of IVF procedures in 1986 were collected from OTA's survey of centers, published estimates, personal communications, and other sources (21,23). OTA estimates that the average cost of IVF was between $4,000 and $6,000 (median $4,688; see table 8-1). OTA estimates that approximately 14,000 completed IVF cycles were performed in 1987 in the United States. (One estimate places the number of IVF cycles at 21,000 (24).) At a median cost of $4,688 per cycle, this represents a total expenditure on IVF of $66 million in 1987.

Total Expenditures

OTA estimates the total 1987 expenditures on infertility as the sum of the non-IVF and IVF expenditures. To reach a figure for the former, the estimate of 1980 non-IVF expenditures is inflated by 10 percent each year to reflect changes in the cost of medical care and in the incidence of infertility diagnosis and treatment. This raises the 1980 estimate of $480 million to about $935 million in 1987. Together with IVF expenditures of $66 million, total infertility expenditures in 1987 are therefore estimated at $1.0 billion.

This approach assumes that the treatment of infertility has not changed "structurally" (e.g., in the relative expenditures on hospital services v. doctors) since 1980. It also assumes that IVF does not replace previous treatments, but represents a new, supplemental cost.

THIRD-PARTY REIMBURSEMENT

Conventional infertility treatment services may be covered by insurance, as long as they can be associated with medical conditions or diseases requiring diagnosis and/or treatment and not solely related to infertility and fertilization. However, this coverage is specific to each insurance plan, varying among underwriters, group policy purchasers, and geographic location (10). Of total U.S. non-IVF infertility expenditures (estimated in the previous section as $480 million in 1980), private insurance paid 70 percent and individuals paid 22 percent out-of-pocket, with the remainder paid by other sources.

While individuals paid 12 percent of hospital costs related to infertility, they paid 38 percent of physician charges. As would be expected, individuals paid a larger share (64 percent) of physician charges under $101 than of charges over $300 (13 percent).

In 1986, some 2.3 million organizations in the United States had health care plans, and 176,424 of these (8 percent) were reportedly self-funded (10,16). There are currently no comprehensive data available that detail the number of these third-party plans providing infertility coverage or the extent of this coverage. However, several general comments can be made about the provisions of these programs that can be applied to infertility coverage.

Examination of third-party reimbursement for infertility services must take into account that the technology applied to these services and to medical treatment in general is changing rapidly, as is the structure of third-party reimbursement, and that both of these trends can evoke a variety of responses. In the case of technology, for example, IVF, which was initially introduced to the United States in 1981, is still considered by many third-party payers to be "experimental" and therefore not insurable. At the same time, however, some carriers provide largely routine coverage for IVF, a rather remarkable development in such a short time (22).

With respect to the structure of third-party reimbursement, there has been a dramatic shift away from traditional group health insurance (Blue Cross/Blue Shield) and commercial insurance), which accounted for roughly 95 percent of the total as recently as 1980; some forecasts indicate that these traditional insurance plans may account for as little as 5 percent by 1990. Much of the shift is to health maintenance organizations (HMOs) and to preferred provider organizations, which did not even exist in 1980. As much as 25 percent of the total by 1990 may be under "managed care" plans, also a creature of the 1980s.

In general, most of these health care plans offer benefits that are a standard package of hospital, surgical, and medical services, with or without major medical or comprehensive provisions. Once these basic provisions are met, the insurer will normally be willing to tailor provisions to the tastes of the buyer. This tailoring may apply, for example, to combinations of deductibles and copayments, specific exclusions, and special additions to normal coverage. The most important variable here is typically the availability of premium dollars, since most group plans are experience-rated.

Given the fact that cost containment has been the dominant theme of both health insurers and employers during the 1980s, there is reason to believe that many group health plans may have chosen to restrict coverage for certain "fringe" services, of which infertility treatment is an example. Since many people still have a variety of moral and ethical concerns in reference to some infertility services, restrictions based on the source of eggs and semen (i.e., spouse versus donors) will undoubtedly continue to appear in some plans for years ahead.

Recent Developments in Insurance

Delaware

In Delaware, a statewide program was instituted by its Blue Cross/Blue Shield Association in response to a nearly successful attempt to have coverage mandated by the State. Since January 1, 1987, employees of the State of Delaware have been covered for IVF and employees of midsize firms (300 to 500 employees) have been offered coverage as a rider (21). Large employers have the option to purchase IVF coverage as their contracts are renewed throughout the year.

Delaware Blue Cross/Blue Shield does not require patients to undergo a minimum waiting period, although all other means, with the exception of tubal surgery, must be tried by the patient. The actuaries anticipate that some of the IVF costs will be offset by a reduction in the use of tubal surgery. Although no restrictions apply to the number of cycles a person may attempt or the cost per cycle, a lifetime maximum of $25,000 will be paid; for artificial insemination, the lifetime limit is $600, although either donor or spousal sperm will be covered.

Surgical procedures, including tubal reconstruction, are covered if medically necessary, but not simply to reverse previous contraceptive sterilization. Delaware Blue Cross/Blue Shield routinely covers surgical sterilization without medical necessity, on request (10). Company actuaries estimate that 90 to 95 percent of costs per cycle will be reimbursed by the insurance plan. The cost of insurance is about $0.60/person/month.

Maryland

In Maryland, the State has mandated coverage of infertility treatments. However, this mandate does not require coverage for artificial insemination, a treatment that normally precedes IVF, but Blue Cross/Blue Shield added this to its policy to assure that this less costly procedure would be attempted before IVF (10). Aside from the mandated IVF benefit, the standard Blue Cross/Blue Shield contracts in Maryland cover all other infertility services on the same basis as other medical procedures. If the group contract provides for diagnostic services (which 90 percent of their contracts do) or drug coverage (75 percent of basic contracts and 95 percent of major medical contracts do), they are covered in the same manner for infertility services as for any other. Similarly, the same rules apply for deductibles (usually $100 to $200), coinsurance on major medical (normally 80 percent), and out-of-pocket limits on major medical expenses. About half the policies have such a limit, usually in the $2,500 range (10).

Attempts by the insurance industry in Maryland to limit coverage to five IVF cycles were defeated, and in 1985 insurance plans were required to offer benefits for IVF at the same level as benefits for other pregnancy related procedures [Maryland Insurance Code Secs. 354DD, 470WW, 477EE, 1987]. This coverage extends to the insured and the insured's spouse. At the same time, some important restrictions on coverage were put in place:

- The couple seeking IVF treatment must be using their own gametes.
- The person seeking IVF treatment must have been seeking infertility treatment for at least 5 years, or the infertility must be associated with one or more of the following conditions: endometriosis, exposure to diethylstilbestrol, or blockage or surgical removal of one or both fallopian tubes (it is not clear whether reversal of voluntary sterilization would be covered); however, IVF benefits for couples with male-factor only infertility are not covered.
- The person seeking IVF treatment must have exhausted all non-IVF treatments covered under the insurance plan.
- Only outpatient services are covered.
- The IVF procedures must be performed at a facility that conforms to the American College of Obstetricians and Gynecologists (ACOG) guidelines for IVF clinics or the American Fertility Society's (AFS) minimal standards for IVF programs.

Although the State mandated coverage by all insurance carriers, not everyone in Maryland is, in fact, covered. Since the State has no jurisdiction over Federal or municipal employees, the legislation does not apply to them. Consequently, neither Federal employees working or residing in Maryland nor employees of the City of Baltimore are covered. Furthermore, the mandate does not apply to groups that are self-insured. Many, if not most, organizations with 500 or more employees have Administrative Services Only contractual arrangements with an insurance carrier, whereby the insurer provides only administrative services and the benefits are self-insured. As a result, most employees of large organizations in Maryland may not be covered for IVF. In addition, Maryland's mandate to provide insurance coverage for IVF does not apply to its Medicaid program. The current cost charged by Blue Cross/Blue Shield in Maryland averages $1.06/household/month, and the company anticipates that 75 to 80 percent of IVF expenses will be reimbursed by the plan.

Hawaii

Hawaii's legislation (Act 332, 1987), effective June 26, 1987, states that all individual and group health insurance plans that provide pregnancy-related benefits must provide, in addition to any other benefits for treating infertility, a one-time-only benefit for the outpatient expenses resulting from IVF for the insured or the insured's spouse. The one-time-only benefit is considered one IVF cycle. Restrictions on eligibility do not differ from those in Maryland except that abnormal male factor contributing to the infertility is also considered an indication for IVF treatment.

Texas

In Texas, legislation effective September 1, 1987 (Act HB 843, 1987), requires that all insurers or administrators of group health insurance policies, self-insured plans, and all health maintenance organizations must offer benefits for IVF in all plans that have maternity benefits. The policyholder does not have to accept these benefits. The benefits must be provided to the same extent as benefits provided for other pregnancy-related prodedures under the policy. Only an insurer affiliated with a bona fide religious denomination that objects to IVF for moral reasons is exempt from the requirement to offer coverage for IVF. The restrictions on eligibility in Texas, like those in Hawaii, state that oligospermia is also an indication for treatment.

Arkansas

Arkansas legislation in 1987 (Act 779, 1987) directed the Insurance Commissioner to issue regulations setting benefit levels for IVF coverage. The regulations, effective December 31, 1987 [Regulation No. 1 (Nov. 18, 1987) pursuant to Act 779 (1987)], require that insurance policies offering maternity benefits offer IVF benefits as well, at the same level as those for maternity. Restrictions are basically the same as those in Hawaii except that the couple need only have a 2-year history of unexplained infertility, and a woman who has been voluntarily sterilized is explicitly ineligible. Cryopreservation is specifically included as an IVF procedure. The IVF must be performed in a State-licensed or certified facility, with the Department of Health in charge of licensing and certifying. However, if no such facility is licensed or certified in Arkansas or no such licensing program is operational, then coverage shall be extended for any procedures performed at a facility that conforms to the ACOG guidelines for IVF clinics or to the AFS minimal standards for programs of IVF. Finally, a lifetime maximum benefit is set at $15,000, which may also include other infertility treatments.

Massachusetts

Legislation in Massachusetts is more extensive than in the other States. In 1987, the Commonwealth of Massachusetts enacted legislation requiring that insurance plans covering pregnancy-related benefits provide coverage for medically necessary expenses of diagnosis and treatment of infertility to the same extent that benefits are provided for other pregnancy-related procedures (Act H 3721, 1987). Infertility was defined as "the condition of a presumably healthy individual who is unable to conceive or produce a conception during a period of one year." The resulting regulation on infertility benefits promulgated by the Division of Insurance outlined these benefits in more detail [211 C.M.R. 37.01 to 37.11, pursuant to Mass. Gen. Law chs. 175 and 176 (1987)]. Both the legislation and the regulations went into effect January 6, 1988.

Under the new regulations, insurers must provide benefits for all nonexperimental infertility procedures. These include, but are not limited to, artificial insemination, IVF, and other procedures recognized as generally accepted or nonexperimental by the AFS, ACOG, or another infertility expert recognized as such by the Commissioner of Insurance. Gamete intrafallopian transfer is considered experimental, and surrogacy, reversal of voluntary sterilization, and procuring donor eggs or sperm are specifically excluded. The insurers may establish reasonable eligibility requirements that must be available to the insured and the Commissioner upon request. The regulations suggest that standards or guidelines developed by AFS or ACOG may serve as eligibility requirements.

Private Insurers

The Prudential medical insurance programs recognize infertility as an illness, and routinely cover virtually all related services, including artificial insemination (restricted to only husband and wife, no donors or surrogates) and IVF, so long as the services conform to ACOG standards and are determined to be medically necessary. Drugs, such as clomiphene citrate and human menopausal gonadotropin, are covered, dependent on the plan (i.e., whether drugs are covered for other purposes). Deductibles, copayments, and out-of-pocket limits are the same for IVF as for all other covered services (10).

A number of insurance company representatives contacted specifically noted, however, that even under plans where no IVF or other infertility coverage exists or is intended, many if not most individual procedures can individually "slip by the screens." If claims for services are submitted by a physician as "medically necessary" and the word "infertility" does not specifically appear, coverage is more likely to result (10).

Future Developments

Future developments for third-party reimbursements are difficult to predict because of the changing structure of the health care delivery systems as well as the rapid development of innovative technologies. However, some general trends may be predicted:

- Greater movement by all types of insurers toward requiring preauthorization for an increasing number of services, second opinions for elective surgery, and a variety of other controls that do not deny coverage, but that tend to control utilization. Although many of these techniques originated in the context of "managed care" situations, they are now being adopted in virtually all settings.
- Lifetime limits and limited cycles of treatment in a given time period applied to some infertility treatments, and selective coinsurance applied to others.
- A growing proportion of infertility services being performed on an ambulatory basis, driven in that direction both by the pressure generated by these selective insurance provisions and, quite independently, by rapid changes in medical technology (10). As some of the more expensive infertility treatments grow in acceptance (because they are better known, clinically proven, and no longer experimental) and demand (because they will increasingly be covered), more infertile couples will be shielded by out-of-pocket limits.
- An increased number of States mandating infertility coverage (see table 8-7) (10,20).

Table 8-7.—Status of Insurance Coverage for Infertility

State/jurisdiction	Legislation exists	Legislative activity	No legislation on infertility
Alabama			X
Alaska			X
Arizona			X
Arkansas	X		
California		X	
Colorado			X
Connecticut		X	
Delaware		X	
District of Columbia			X
Florida			X
Georgia			X[a]
Hawaii	X		
Idaho			X
Illinois			X
Indiana			X
Iowa			X
Kansas			X
Kentucky			X
Louisiana			X
Maine			X
Maryland	X		
Massachusetts	X		
Michigan			X
Minnesota			X
Mississippi			X
Missouri			X
Montana			X
Nebraska			X
Nevada			X
New Hampshire			X
New Jersey			X
New Mexico			X
New York			X
North Carolina			X
North Dakota			X
Ohio			X
Oklahoma			X
Oregon			X
Pennsylvania			X
Puerto Rico			X
Rhode Island			X
South Carolina			X
South Dakota			X
Tennessee			X
Texas	X		
Utah			X
Vermont			X
Virginia			X
Washington		X	
West Virginia			X
Wisconsin		X	
Wyoming			X

[a] However, the Georgia insurance department routinely requires all insurance carriers to cover infertility treatment except for experimental procedures, and IVF is currently considered experimental (R. Terry, Chief Deputy Commissioner, Regulatory Law Division, Office of Commissioner of Insurance, Atlanta, GA, personal communication, September 1987).

SOURCE: Office of Technology Assessment, 1988.

The demand for health services, both in the United States and around the world, has always been significantly influenced by the level of third-party reimbursement. Thus, assuming that most infertility services are eligible for at least some level of coverage, and that the overall level of reimbursement improves, demand can be expected to increase. When this will occur is difficult to predict. There is generally a timelag between the introduction of new coverage and the increase in demand. This is explained by the learning curve of consumers and providers of care, who do not immediately perceive the change and therefore require some time before altering their behavior. Another factor that may contribute to an increase in demand is improvement in expected results (i.e., technology). This may be a particularly important factor in relation to infertility services.

With the advent of IVF, gamete intrafallopian transfer, and other new reproductive technologies, the issue of insurance coverage has become more controversial and more influential in determining what types of treatment are sought and provided.

A major concern of insurers is to protect themselves from covering risks where the likelihood of the event occurring can be influenced by the insured party. This concern is generally referred to as moral hazard. Insurers who underwrite such risks could be subject to adverse selection. In their quest for a "fair bet," insurers will often pass up an insurable risk when they think they cannot at reasonable cost protect themselves from adverse selection. Insurance markets can fail altogether if insurers think they are buying a risk but are in fact buying a certainty.

Even if they can arrange a fair risk, insurers do not want the amount at which they are at risk to be extremely large. Furthermore, they prefer to insure events where the likelihood of the event occurring is known rather than uncertain. Finally, health insurers try to avoid covering procedures that have not met with general approval and that may be difficult to sell to policyholders. Examples include costly experimental procedures the efficacy of which has not yet been proved and procedures for which a societal consensus has not yet developed.

Coverage of IVF procedures poses several problems for insurers. First, IVF belongs to a class of risks where the purchasers of insurance may have better information than the insurer at the time of purchase regarding the likelihood that they will need the procedure. Using the same reasoning, insurers resisted coverage of pregnancy for a long time. They considered having a child to be a choice, not an unforeseen event, and believed that couples wishing to have a child should, therefore, simply save for that event. Unless all insurers provided pregnancy benefits (or IVF benefits), an insurer might fear that persons knowing in advance that they wanted children or needed IVF would sign up for that company's insurance.

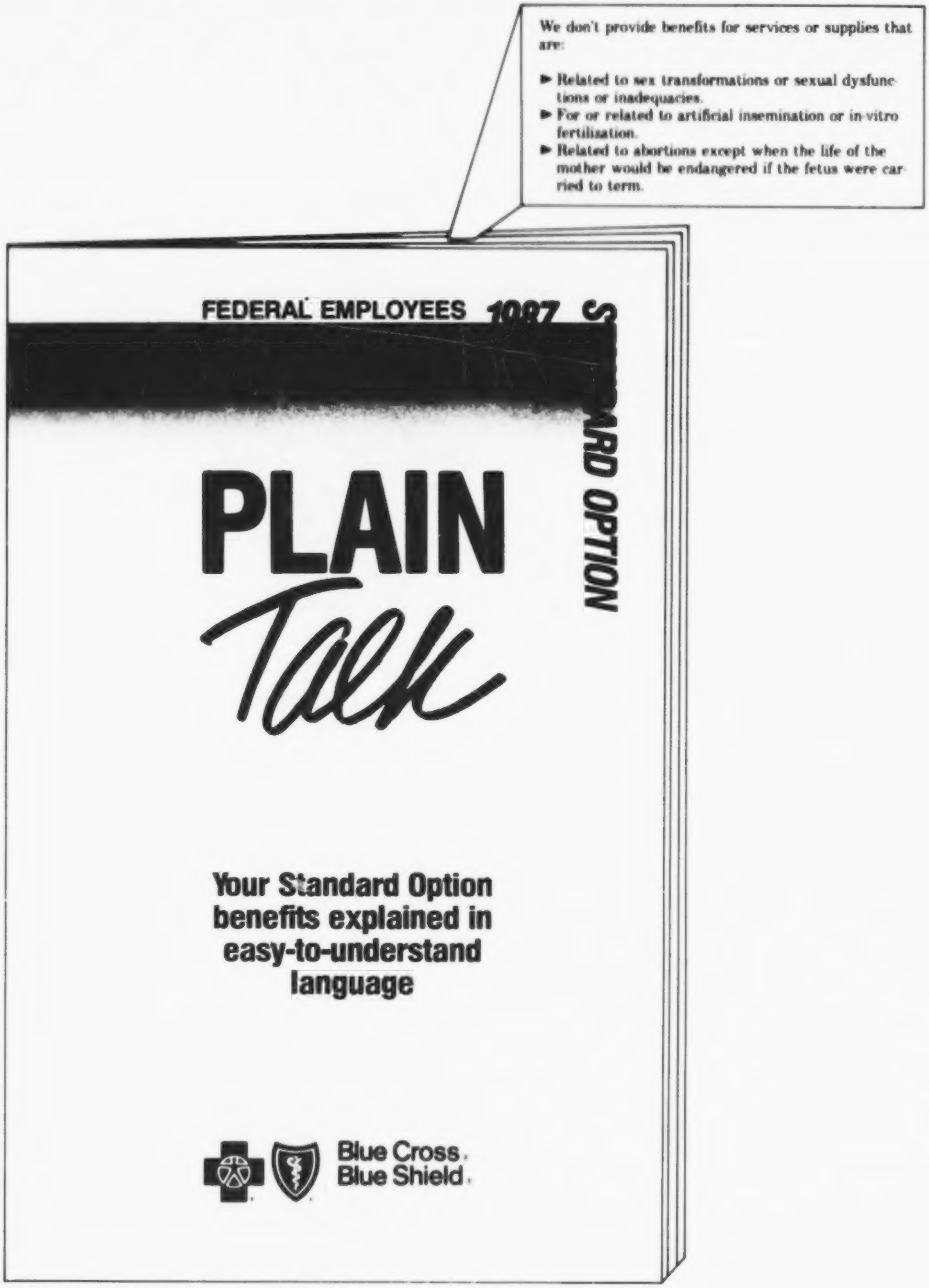
In addition, the potentially high cost of IVF combined with a perception of low success makes it difficult to sell premium increases to policyholders. That IVF is perceived to be a procedure of uncertain benefit to a few at the expense of many has served to further deter insurers from entering this market.

When insurers do undertake to insure events where adverse selection is likely, where the possible losses are high or the risks not well known, or where it may be difficult to sell the need for the procedure to large employer/employee groups, they try to institute mechanisms to protect themselves. When this is not yet reasonably possible and, for reasons of social policy, it is desirable to protect certain individuals, then the risks are often borne by society as a whole through social insurance schemes (e.g., Medicare and Medicaid).

The majority of health insurance plans and health maintenance organizations exclude specific coverage for IVF (22). Typical is the language used by Blue Cross/Blue Shield in its coverage of Federal employees under the Federal Employee Health Benefits Program (FEHBP) (see figure 8-2). These programs state that they exclude from coverage artificial insemination by donor, IVF, and reversals of sterilization (10,21).

However, even though the majority of providers exclude IVF, this coverage may be increasing. A recent survey conducted by the Health Insurance Association of America of its 20 largest companies plus a random sample of 80 other members produced rather surprising results (22). While large companies were more likely than small companies to provide IVF benefits, there was little difference between coverage in group versus individual policies. On a weighted basis, an estimated 41 percent of those covered under group policies and 40 percent of those covered by individual policies currently have coverage for at least most of the services associated with IVF, though a variety of restrictions exist, particularly with respect

Figure 8-2.—Typical Language Describing Health Care Benefits Related to IVF and Artificial Insemination



We don't provide benefits for services or supplies that are:

- ► Related to sex transformations or sexual dysfunctions or inadequacies.
- ► For or related to artificial insemination or in-vitro fertilization.
- ► Related to abortions except when the life of the mother would be endangered if the fetus were carried to term.

FEDERAL EMPLOYEES 1987 STANDARD OPTION

[redacted]

PLAIN Talk

Your Standard Option benefits explained in easy-to-understand language

Blue Cross. Blue Shield.

SOURCE: Office of Technology Assessment, 1988.

to the source of egg and sperm. These figures are based on a question that referred to "typical" group and individual policies.

In a followup question, virtually all of the large and none of the small insurers who did not provide for IVF in their most typical policy did make the option available under other policies upon request for the benefit by the policyholder. The most common reason for not covering IVF under both group and individual contracts was that "it is not the treatment of an illness." The next most common reason given was that "it is still an experimental treatment." Claims evaluation is done on a case-by-case basis, with no standard practice identified by most carriers (10).

Despite the continued exclusion of IVF from coverage by a majority of insurers, OTA estimates that for the current patient population, insurance coverage is actually considerable for many aspects of the IVF workup and treatment procedures. If insurance claims for each of the individual diagnostic and treatment components of IVF are submitted separately, then the cost of the components may be reimbursed. One center reported that laparoscopies performed as part of an IVF procedure were covered by insurance at a reimbursement level that averaged 70 percent (21).

THE COST OF INSURANCE

As mentioned earlier, the extra cost of IVF coverage has been estimated by actuaries at Blue Cross/Blue Shield to range from $1.06/household/month in Maryland to $0.60/person/month in Delaware. It is important to recognize that these are short-term estimates. They have not been developed using estimates and projections of the incidence and prevalence of infertility or an estimate of the likely demand for IVF. They are based on the number of IVF services currently available and upon the assumption that every one of the currently available services will be used.

For example, actuaries for Maryland Blue Cross/Blue Shield surveyed the IVF clinics in and near Maryland and found that the potential treatment capacity for these clinics in 1985 was 800 women per year, and that the average cost per patient would be $12,800 based on three treatment cycles per patient, with varying degrees of success. The total cost for all 800 women treated in or near Maryland would therefore be about $10.2 million; it was assumed that Blue Cross/Blue Shield of Maryland would be responsible for about half the amount, or $5.1 million. They then assumed that capacity would grow by 33 percent in 1986, so that the estimated total cost to them in 1986 would be 1.33 times $5.1 million, or about $7 million. Distributing this sum over the 550,000 households that would be insured for this coverage yielded the rate of $1.06/household/month (21).

Where the demand for services is unknown, the supply of services is well known, and demand is thought to greatly exceed supply, near-term estimates based upon supply alone are reasonable and quite accurate. The estimation by Maryland Blue Cross/Blue Shield actuaries was done in June 1985. As of December 1, 1986, about 300 patients had applied for reimbursements of IVF expenses. Given the lag both in starting the program and in reporting by patients, it appears that the estimate of patient utilization was accurate. Unknown at this point is whether the estimates of the number of treatments per patient or the cost per treatment were close. Finally, Blue Cross/Blue Shield built into its rates a margin of error of at least 20 percent. They estimate that, after deductibles and coinsurance, they will only reimburse about 80 percent of charges.

Estimates of long-term or equilibrium costs of IVF coverage will have to be based on experience with the need and demand for services, and especially with the effect insurance will have on such demand. This will require a close look at the incidence of infertility, especially the kind for which IVF is a preferred procedure; at the cost structure of the industry that underlies the supply price; at the availability and demand for substitute procedures; and at the effect of insurance on the demand for IVF and non-IVF services.

Public Programs

Coverage for infertility services by Medicaid varies among State programs. In the Federal Medicaid program many infertility services can be covered under the "family planning services" category. Many State programs will pay for drugs, counseling, and surgical procedures, including sterilization reversals if deemed medically necessary.

At present, no Federal Government programs cover IVF procedures. Furthermore, no Government health facility, such as those operated by the Department of Defense or the Veterans' Administration, has been identified that provides IVF services. However, just as the commercial insurance industry appears to be paying for some portion of the IVF expense even when its policies explicitly exclude such procedures, Government reimbursement programs may be paying for some of these benefits as well.

Although the Federal Medicaid program does not restrict State provision of IVF procedures (10,21), OTA has not identified any State program that has paid out IVF benefits. However, the District of Columbia, which appears to have the most liberal medical coverage in the country, may be an exception. It reported that it covers all types of infertility services. Though it had not received any requests for IVF, if they do come, it would "probably pay them" (10).

As with private insurers, it is likely that some IVF component services are inadvertently paid by most Medicaid plans. This "leakage" is far less likely to occur under HMOs and "managed care" plans. For the unwitting reimbursement of IVF charges by insurance carriers to occur, however, patients must have sufficient resources to pay the clinic and await reimbursement. This is a possibility for persons covered by private insurance and the Civilian Health and Medical Program of the Uniformed Services, but Medicaid beneficiaries are unlikely to have such resources. Therefore, it is unlikely that most Medicaid programs cover IVF benefits directly, although there may be partial coverage of various components of the IVF workup, such as ovulation induction or laparoscopy.

Federal Employee Health Benefits Program

The approximately 3 million current civilian employees of the Federal Government are covered by 435 different health plans nationwide. Although some smaller local health plans may provide IVF coverage, the U.S. Government Office of the Actuary could not readily identify any (21). As mentioned, the large nationwide plans serving Federal employees, such as Aetna and Blue Cross/Blue Shield, specifically exclude IVF, reversals of sterilization, and artificial insemination (21). Despite these specific exclusions, these plans may be providing some reimbursement for IVF components, as described earlier. HMOs, on the other hand, are more able to control patient utilization of infertility services and are therefore less likely to reimburse IVF-related charges.

The cost of extending insurance coverage for IVF to Federal civilian employees can be roughly estimated. There are about 690,000 female employees of the Federal Government between the ages of 15 and 44, and 1.2 million male employees aged 20 to 49. Some 52 percent of females between 15 and 44 are married (21). If this percentage holds for Federal employees as well, then about 360,000 female employees are married. If half the male Federal employees are married to women between 15 and 44, then there are 600,000 women between 15 and 44 married to male Federal employees. Altogether, that yields 960,000 couples with female partners between the ages of 15 and 44 potentially eligible for Federal insurance coverage (assuming for the sake of these rough estimates that Federal employees are not married to each other).

Assuming that 8.5 percent of married women between 15 and 44 were part of an infertile couple, and applying that rate to women covered by Federal plans, then 81,600 of these couples would be infertile. On average, approximately 31 percent of infertile couples seek infertility treatment (13). This would suggest that about 25,000 infertile couples who are eligible for Federal employees' insurance coverage seek infertility treatment. OTA estimates that at the present level of practice, only about 11 percent of those who seek infertility treatment actually undergo IVF procedures. Thus the current number of female Federal employees who would undergo IVF is 2,783.

If the average cost of IVF treatments is between $4,000 and $6,000 per treatment cycle (see table 8-1), with on average two treatment cycles per patient, the current cost per patient is between $8,000 and $12,000. For the 2,783 women covered by FEHBP, the total expenditure for IVF would be $22 million to $33 million.

IVF/INFERTILITY CENTERS

This section provides a more detailed profile of IVF/infertility centers, focusing on their operations and the characteristics of the market in which they operate (21). Profile characteristics discussed include the organizational status of the clinics (nonprofit or for-profit), their size and age, funding sources, types of services offered, demand for services, barriers to entry, and future trends. In general, IVF/infertility facilities are well distributed geographically and evenly split between profit and nonprofit operations (see app. A). Most offer a variety of infertility services and are not limited to IVF.

General Operating Characteristics

OTA has identified 169 IVF/infertility centers in the United States as of early 1988. Most of these are listed with the American Fertility Society as offering IVF (2). However, it is estimated that only 80 to 90 of these centers are established facilities with particularly active programs (14). IVF/infertility centers are located in 41 States, the District of Columbia, and Puerto Rico; only five States have 10 or more centers (California with 22, Florida with 10, New York with 11, Ohio with 10, and Texas with 14).

Although the centers are fairly well distributed around the country, it should be noted that even on a State-by-State basis, infertile couples seeking services in nine States must travel elsewhere for treatment (see figure 8-3).

Most, though not an overwhelming majority, of IVF/infertility centers in the United States are nonprofit. The predominant organizational arrangement is a nonprofit infertility center that is part of a nonprofit university or hospital. The remaining centers include independent, for-profit outfits and for-profit centers affiliated with a nonprofit institution (such as hospitals or universities).

Most IVF/infertility centers are relatively small, rarely exceeding 20 staff. Typically, the staff includes:

- one or two physicians specializing in reproductive endocrinology,
- one doctorate-level scientist (reproductive biologist),
- two to four registered nurses,
- one to six technicians, and
- one psychologist or counselor (see box 8-A).

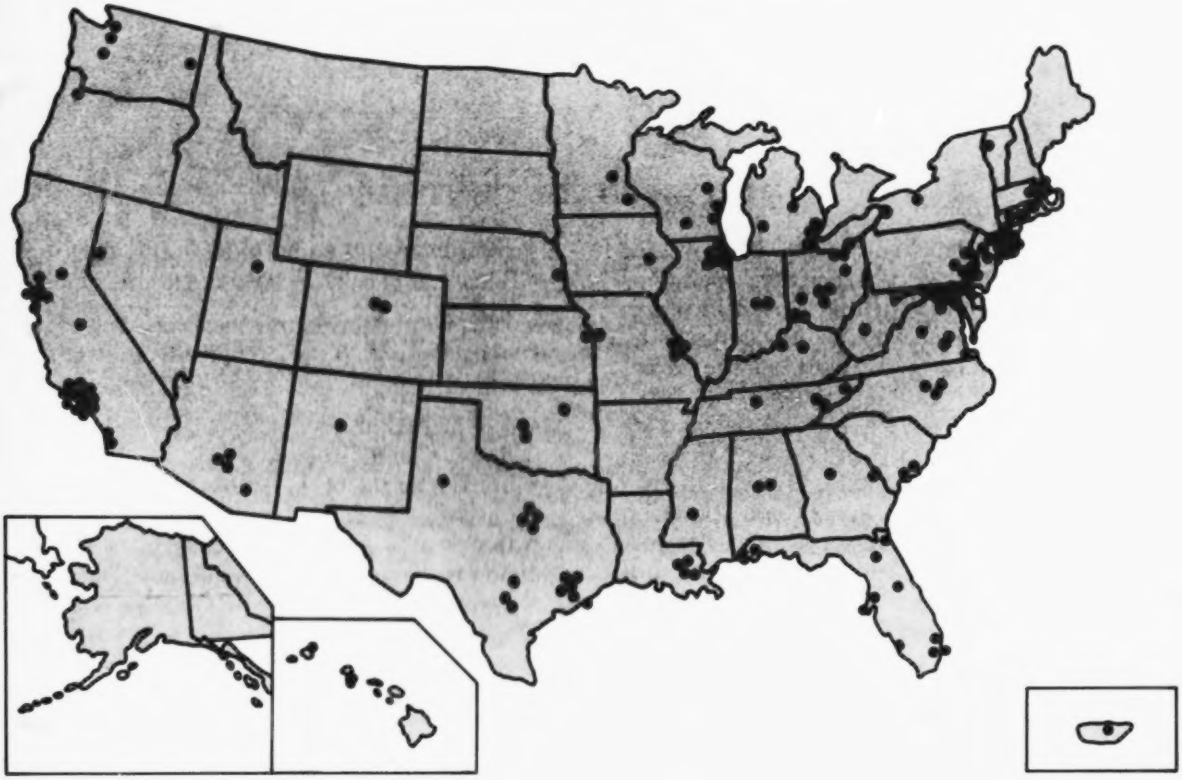
Type of Services Offered

These centers generally offered a variety of services in addition to IVF, including microsurgery. A growing number also offer alternative reproductive technologies such as gamete intrafallopian transfer and tubal ovum transfer. Yet a small but increasing number offer only IVF.

Some IVF/infertility centers have restrictive policies as to the types of patients they will serve. These policies include not serving individuals without partners, treating only married couples, age restrictions (no services to those under ages 17 to 20 or over ages 39 to 50), and restrictions on treatments of homosexuals. No pattern of restrictions related to the organizational status of the clinics appears present.

Most centers offer a variety of the well-established infertility diagnostic and treatment services. The only major exception is male microsurgery and artificial insemination. As expected, many IVF clinics appear to be much more oriented toward female microsurgery and treatment than treatment of male infertility.

Figure 8-3.—Distribution of IVF/Infertility Centers in the United States



SOURCE: Office of Technology Assessment, 1988.

A second item of interest is that many facilities do not yet offer the latest techniques and advances in infertility treatment (such as embryo freezing, laser laparoscopy, or even frozen donor sperm for artificial insemination). The lag time for diffusion of new technology appears to be on the order of at least 2 years.

Funding Sources

Patient fees account for the largest source of funds for the IVF clinics, in general making up 80 to 100 percent of revenues. Aside from a small number of IVF/infertility clinic that treat many Medicaid patients, most programs receive less than 10 percent of total funding from Medicaid funds. Other sources of funding for IVF centers include university subsidies and private research grants.

Demand for Services

The majority of IVF programs in the United States have a waiting list of patients. Although the older, more established programs can have waiting lists as long as 1 to 2 years, this is not the case with the smaller, recently started programs.

IVF/infertility centers receive a small amount of referrals from hospitals. A major source of patients for most IVF clinics is referrals from physicians. But referrals from other patients or self-referrals by patients appear to be equally, if not more, important for IVF clinics.

As the demand for infertility services has grown, some couples with diagnosed or suspected infertility problems may place themselves on one or more IVF center waiting lists even before other

Box 8-A.—Integrating Psychological and Medical Treatment

Many couples surveyed at infertility clinics say they wished they had been offered psychological counseling during their treatment. Issues identified by infertile people as a potential focus for counseling include problems in the marital relationship, sexual dissatisfaction, crisis reactions, anxiety surrounding efforts to achieve a pregnancy, and alternative solutions to involuntary childlessness.

There are at least four ways that infertility clinics try to meet the psychological needs of their patients. Most common is to rely upon professional medical staff to be sensitive to the emotional stress of infertility diagnosis and treatment. Others use a consultant on a case-by-case basis. The consultant is alerted by medical staff when an individual or a couple exhibits emotional distress, particularly if their anxiety is interfering with the successful outcome of treatment.

Some clinics have a professional counselor on their staff. Usually this person's responsibilities involve meeting with each individual or couple on their first visit to orient them to the clinic services. At this time the professional also may make an effort to alert patients to the potential emotional strains of the diagnosis and treatment experience. Community resources are often mentioned at this time, particularly any nearby support groups of infertile people who meet on a regular basis.

Still other clinics have adopted a preventive mental health approach, in which each individual meets with the counseling professional on the first visit, both as a way of learning what to expect from the clinic, to explore his or her present emotional state, and to help develop acceptance of the stress infertility and its treatment can cause. The professional then offers ways to cope with the emotional distress for clinic patients, including regular visits with all patients, short-term counseling for particularly stressful times, referrals to community professionals for long-term counseling, and an invitation to join a support group of infertile patients conducted by the professional in the clinic. The professional may make daily visits to the surgical ward of the hospital, both to discuss patient apprehensions prior to surgery and to offer support and advocacy during a hospital stay.

Some infertile people may choose to decline these various offers of psychological counseling. Clinic-based counseling may be inconvenient if the patients live far from the site or visit it infrequently. Some may be reluctant to place in clinic records any information that may influence judgments about their acceptability as candidates for medical or surgical treatments, or for noncoital techniques for achieving pregnancy. Others may find the clinic staff insensitive, or feel that even well-meant offers of counseling are nonetheless unnecessary or intrusive. They may not care for this type of professional counseling, and prefer to seek help from family, friends, support groups, or outside professional counselors.

SOURCE: Office of Technology Assessment, 1988

non-IVF infertility treatments have been attempted. The extent of this practice is unknown. Despite the waiting lists, there also appears to be a growing amount of competition among IVF centers located in large metropolitan areas or among programs within the same general geographical area. Competition may increase as the number and efficacy of the infertility treatments improve.

Opening Up New Centers

To what extent is it difficult for infertility clinics to expand into the market for IVF services? Most IVF clinics begin as adjuncts to departments of obstetrics and gynecology that have been involved in infertility services for years and want to include this new technology. Although IVF requires a good deal of specialty equipment and labor, much of each is generally available in most hospitals. As a result, IVF clinics can often begin operation without equipment and labor specifically dedicated to IVF, as indicated by the wide range in the number of IVF cycles conducted around the country. Although the large, well-known clinics operate at the level of 800 to 1,000 treatment cycles per year, some programs perform fewer than 50.

The coexistence of clinics doing 50 and 800 cycles per year indicates the ease with which a viable clinic can be organized and run from an existing medical facility. The major items of equipment required for ovum preparation and embryo transfer include an incubator, high-purity water system, autoclave, and low temperature freezer to freeze embryos. The cost of purchasing this equipment has been estimated as in the neighborhood of $40,000 to $60,000 (21), although the actual cost may be as high as $100,000 (14).

The remainder of equipment needed, such as microscopes, video camera and monitor for the laparoscope, and all the hospital and surgical equipment, is generally priced internally so that little of the cost is passed on to the IVF facility. In addition, the services of technicians and an embryologist can generally be found in the hospital, so these specialty labor costs can also be priced at the margin. Finally, an expanding obstetrics/gynecology facility will not have to incur the expense of waiting and examining rooms. Thus if demand increases substantially due to wider insurance coverage of IVF, enhanced effectiveness of IVF, or a change in the public's perception of the cost and effectiveness of IVF, supply can be expected to increase to meet the new demand without necessarily encountering bottlenecks.

Future Trends

New developments in infertility diagnosis and treatment have the potential to revolutionize the way services are demanded and offered. A number of trends in particular could significantly affect the estimates developed in this section.

Charges for IVF and other infertility treatments can be expected to continue to increase in the next few years. In addition to the rise in fees associated with increases in all health care, some increases will result from the raising of fees as individual programs become more established and accomplished with the various techniques. Neither competition among facilities nor increased success rates for procedures such as GIFT and IVF are likely to reduce infertility costs drastically in the near future.

The majority of IVF/infertility centers will continue to introduce new procedures to their practices in the near future. In particular, many centers intend to expand into embryo freezing, the cryopreservation of oocytes, and the use of donor oocytes and embryos in IVF for women unable to produce eggs. Other techniques that are offered at some clinics but that have not yet been disseminated throughout the industry include laser laparoscopy, GIFT, intrauterine insemination, surrogate pregnancies, artificial insemination with frozen donor semen, artificial insemination with sex selection, and ultrasound-guided vaginal oocyte retrieval.

Other areas of likely expansion for IVF/infertility centers include andrologic diagnosis and treatment, immunologic studies, embryo transfer, estrogen replacement therapy, gamete manipulation, hormone evaluation and treatment correlation, and possible changes in the fertility drug stimulation regime for IVF and GIFT.

Most IVF/infertility centers agree that changes in third-party reimbursement policy would affect the number of patients seeking infertility services. Expanded insurance coverage of IVF and GIFT services could have a significant impact on the demand for these services. Couples who cannot currently afford IVF or GIFT, or who cannot afford more than one cycle, would be able to undergo the procedures. This expanded group would include both couples who are now "doing nothing" in the absence of IVF as well as women who are currently undergoing tubal surgery in lieu of IVF or GIFT. Making IVF or GIFT insurance-reimbursable could in some instances replace low-yield surgical procedures that are currently reimbursed.

SUMMARY AND CONCLUSIONS

Over the last decade infertility services have grown in scope and sophistication. The demand for infertility services has increased as well, to a point where between 300,000 and 1 million couples in the United States seek infertility treatment services annually. Overall, doctors report that half the infertile couples who seek treatment are able to have a baby.

An examination of U.S. expenditures on infertility treatment produced the following key findings:

- *Access to infertility treatment*. For the initial medical consultation on an infertility problem, couples are most likely to seek the advice of their gynecologist, general practitioner, or urologist. Most gynecologists and urologists can provide at least basic infertility diagnostic and treatment services. For problems serious enough for referral to an infertility specialist, access to specialized care is likely to be reduced. Sophisticated infertility care is generally located in urban areas. Procedures for more difficult infertility cases are more likely to be available at universities and medical centers.

  Access to highly specialized infertility treatment, in addition to being geographically determined, is also a function of cost and insurance coverage for many procedures. In general, people with adequate financial resources, either their own or insurance with infertility coverage, have no more difficulty obtaining infertility services than they do most other types of medical care; however, infertility services are less available to low-income couples, and low-income women face serious financial obstacles to obtaining specialized or complex infertility services.
- *Choices of reproductive services*. Infertility treatment represents only one of a number of options for achieving parenthood. Other options that are weighed by infertile couples side by side with medical treatment include adoption, embyro transfer or donation, and surrogacy. For couples with serious infertility problems, the choice of treatment may be made several times and at several points over an extended period of time. In estimating the cost of infertility services, OTA hypothesizes four scenarios typical of female infertility diagnosis and treatment. Medical costs for each of the four stylized scenarios range from $2,055 to $9,376. Viewed together as a four-stage, worst-case treatment process, a couple starting out would have a 69-percent chance of achieving pregnancy (approximately 50 percent chance of a live birth), at a cost of more than $22,000.
- *Costs of infertility services to couples*. Costs to individual couples receiving infertility treatment vary widely, depending on the severity of the infertility problem. Typically, a full diagnostic workup can cost $2,500 to $3,000, although many couples do not need to make such an extensive outlay. In addition to medical costs, couples often incur considerable expenses on travel, lost time from work, and hotel accommodations.
- *Total expenditures on infertility services*. Extrapolating from data from the National Medical Care Utilization and Expenditure Survey of 1980, infertility expenditures in 1987 were estimated to total $1.0 billion. Of that amount, about $66 million was spent on IVF. The remainder was spent on non-IVF infertility diagnosis and treatment.
- *Coverage by third-party reimbursers*. Private health insurance is estimated to cover about 70 percent of infertility expenditures. Couples pay out-of-pocket about 20 percent of the cost of infertility diagnosis and treatment, while other sources such as Medicaid account for another 8 percent. For IVF-related treatment, although the majority of health insurance plans have specifically excluded coverage from their policies, there appears to be a significant amount of reimbursement for the various components of IVF treatment, such as laparoscopy.
- *Insurance perspective on IVF*. IVF is considered to be an expensive item for insurance companies, both because individual components are expensive, and because there is no defined upper limit on the number of times IVF can be undertaken. Insurance companies have therefore been reluctant to underwrite such a large potential liability without placing restrictions on the number of procedures covered. OTA estimates an average of two IVF cycles per patient, suggesting that unlimited IVF cycles per patient are not currently occurring. This figure may increase, however, if more insurance coverage becomes available.

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Chapter 9

Quality Assurance in Research and Clinical Care

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Chapter 9

Quality Assurance in Research and Clinical Care

This chapter concentrates on the role that can be played by medical societies, State governments, and the Federal Government to assure high quality in the provision of four particular reproductive techniques: in vitro fertilization (IVF), artificial insemination by donor, embryo transfer, and gamete intrafallopian transfer (GIFT). Surrogate motherhood raises discrete questions related to the relinquishment of parental rights by women who are gestational mothers, and is considered in more depth in chapter 14.

Quality assurance includes protecting individuals from being offered experimental treatments under the guise of therapy and from the inappropriately enthusiastic use of procedures not yet shown to be safe and effective. In addition, some procedures are accepted medical practice for certain indications but not for others. For example, IVF was originally offered only to women with damaged fallopian tubes, but has more recently come to be used for other types of infertility, including male factor infertility. As indications for use expand, it becomes increasingly important for patients to understand the realistic likelihood of success. Differences in success rates among clinics cannot yet be fully explained, and some clinics have yet to achieve a live birth following IVF.

Another concern in this area is that IVF requires the creation of extracorporeal embryos that may then be donated, sold, frozen, or used in research. Restrictions on these dispositions of embryos are not intended to assure high-quality medical care per se, but rather are an attempt to limit the abuses that could arise as a corollary to creating extracorporeal embryos.

Finally, the use of donated semen poses the risk of disease transmission. Concern over reports of hepatitis B transmission in the United States and human immunodeficiency virus (HIV) transmission in Australia following donor insemination has led to activity in State legislatures (see ch. 13), the Department of Health and Human Services (DHHS), and various professional societies.

Professional societies influence the research and treatment protocols of medical practitioners. Some, such as the American College of Obstetricians and Gynecologists (ACOG), the American Fertility Society (AFS), and the American Association of Tissue Banks (AATB), have issued reports and guidelines on use of donor eggs and sperm, treatment of extracorporeal embryos, and the general assurance of high-quality medical treatment of infertility.

The American Fertility Society, for example, has set up a voluntary registry of IVF and GIFT programs and a special interest group for those who meet certain minimum criteria for staffing and success in achieving pregnancy. Although membership in the special interest group does not confer accreditation, that term has been used by at least one program to help identify itself as meeting certain standards of practice (see figure 9-1). In addition, all registry members are asked to report on their techniques and success rates, so that the efficacy of various IVF and GIFT protocols can be evaluated.

The first part of this chapter discusses the structure of professional medical societies and their potential for providing practitioner education, for setting a standard of care that protects individuals from experimental procedures offered in the guise of therapeutic treatment, for assuring adequate staffing and laboratory facilities for clinics offering such treatments, and for developing a consensus among researchers and practitioners concerning the handling of extracorporeal embryos and the involvement of third parties in conceiving or bearing a child for another person.

Federal authority can facilitate nonregulatory efforts to assure high-quality infertility treatment. Governmental authority can also be brought to bear on these issues with respect to establishing standards of medical practice; approving protocols for research with humans; protecting the extracorporeal human embryo; regulating donor screening and confidentiality; regulating commerce

Figure 9-1.—In Vitro Fertilization Clinic Advertisement Position Available

IVF Laboratory

New York Medical Center: Immediate opportunities to join the laboratory of established AFS accredited program involved in In Vitro Fertilization, GIFT, and Gamete Cryopreservation. Previous experience in gamete culture and manipulation, or in tissue culture and genetics would be an advantage. Master's or Bachelor's degree required. Responsibilities would variously include management and clinical service related to the laboratory, activities such as mouse embryo culture etc., and involvement in research related to the program.

Interested candidates should forward a resume with references

SOURCE: *Biology of Reproduction*, April 1987.

in sperm, eggs, and embryos; and attaching conditions to the delivery of medical services paid for by Government programs or to research financed by Government agencies.

States have actively legislated in areas concerning artificial insemination by donor (see ch. 13), and a number of States have regulations related to fetal research (see app. C). But few have specific statutes on IVF, and no legislation exists on gamete intrafallopian transfer. Since the oversight of medical practice is primarily a State function, regulating these particular technologies will almost always fall primarily to individual States.

The Federal Government has over the last 14 years formed four commissions that have made recommendations on, among other topics, noncoital reproductive techniques: the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; the Ethics Advisory Board of the Department of Health, Education, and Welfare; the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research; and the Congressional Biomedical Ethics Board. The Federal powers to implement the suggestions of these advisory panels are explored near the end of this chapter.

THE ROLE OF PROFESSIONAL SOCIETIES IN ASSURING QUALITY

Membership in a professional medical society is purely voluntary, as is the members' adherence to the organization's medical standards. Physicians are licensed by the State. A medical license not only permits them to practice medicine, but forbids all those without a license from competing by making the practice of medicine without a license a criminal offense. This State license is the only one required to practice medicine or any of its specialties; neither failure to belong to a specialty organization nor failure to maintain such a membership in any way limits a physician's legal ability to practice a medical specialty. Nonetheless, intellectual and economic incentives in the 1930s and 1940s led to the development of certification procedures for specialties, to hospital-based specialty training programs, and finally to the growth in voluntary professional societies of specialists (59).

Professional organizations can set informal standards for clinical care, make their members undergo continuing professional education to maintain active membership status, and require periodic examination and reexamination. A professional organization can also survey its members and gather data on new techniques. Taking part in such studies, however, is purely voluntary on the part of the membership.

In the field of infertility care, one of the most influential medical societies is the American College of Obstetricians and Gynecologists. Members, designated as "fellows," must be licensed physicians certified in obstetrics and gynecology. ACOG's first national Constitution and Bylaws, adopted in 1951, listed among its purposes:

- to establish and maintain the highest possible standards for obstetric and gynecologic

education,
- to perpetuate the history and best traditions of obstetrics and gynecology practice and ethics,
- to maintain the dignity and efficiency of obstetric and gynecologic practice in its relationship to public welfare, and
- to promote publications and encourage contributions to medical and scientific literature pertaining to obstetrics and gynecology (46).

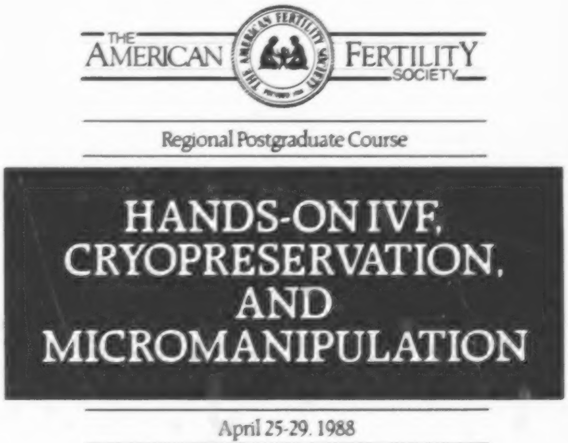
Pursuant to its professional purposes, ACOG has periodically issued statements on the professional and ethical issues raised by use of medically assisted reproduction (3). For example, in 1984 its Committee on Gynecologic Practice classified IVF as a "clinically applicable procedure" (i.e., clinically effective for general or limited use) and then listed personnel and facilities requirements for an IVF program (5). In 1986 its Committee on Ethics issued a statement acknowledging the ethical issues posed by the creation of extracorporeal embryos (4). Statements such as these do not bind a society's members to a particular practice, but do serve to develop some consensus among practitioners.

Similarly, the American Association of Tissue Banks issued a statement in 1984 setting forth the qualifications and training needed to serve as director of a tissue bank, including a sperm bank (2). Further, its Reproductive Council listed a variety of conditions that ought to be sufficient to exclude a person from eligibility as a sperm donor, and proposed a series of examinations that ought to be undertaken to detect those conditions.

Another influential group in this field is the American Fertility Society, open not only to obstetricians and gynecologists, but also to urologists, reproductive endocrinologists, researchers, "and others interested." Its purposes are similar to those of ACOG, and include "extending knowledge of all aspects of fertility and problems of infertility in man and animals."

The AFS Ethics Committee published a report in 1986 that summarized prior AFS efforts with respect to noncoital reproductive techniques (6) and made recommendations for additional action (7). The report noted, for example, the AFS guidelines for minimum staffing, counseling, institutional review, and medical services of an IVF program. These guidelines, and those of ACOG, have been adopted into State law in Louisiana (Act No. 964, 1986), an example of the interaction possible between medical societies and State legislatures. AFS has also initiated a hands-on training program for handling gametes and embryos. Such programs help introduce practitioners to techniques often never seen in medical school or during residency. Of course, short training courses are not equivalent to subspecialty training (12).

AFS recommended in its 1986 Ethics Committee report that IVF clinics develop standard practices for collecting information on pregnancy and live birth rates, for followup on the participants and any resulting children, for genetic screening of gamete donors, and for equipment maintenance. The report stressed the importance of fully



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Source: American Fertility Society

Announcement of Professional Training Course informing potential patients of the success rate and experience of the particular clinic they are visiting, of the availability of alternative therapies or methods to form a family, of the costs they can anticipate, and of the financial or social support they can expect to receive (see box 9-A).

Professional society membership can confuse patients. Numerous organizations, such as the American Fertility Society, are open to anyone who expresses an interest in the area; membership does not necessarily indicate special expertise. Patients choosing a doctor should inquire about a physician's past experience with the infertility treatments and certifications in subspecialties, and not rely only on the physician's membership in a society or attendance at a short, continuing medical education course (12).

Box 9-A.—Questions To Ask Before Beginning IVF Treatment

Before beginning IVF treatment at a particular clinic, patients might want to ask a number of questions, including:

- What is the center's pregnancy rate and how is it calculated? Does the clinic measure success by achieving chemically detectable pregnancies, those confirmed by ultrasound, or live births? What is the most meaningful success rate for this particular IVF attempt, based upon the patient's history of responding to stimulation, transfer, and pregnancy? What is the success rate for patients with similar histories?
- Does the clinic implant all fertilized eggs or only those that appear capable of normal development? Does it limit the number of implanted fertilized eggs to minimize risks associated with multiple births? Can the clinic freeze extra embryos for subsequent attempts? What has been the clinic's rate of loss for those embryos?
- Does the clinic offer psychological counseling or have a regular means of referral for those patients who seek help? Is it coordinated with the medical workup and transfer attempts, to anticipate difficulties or disappointments?
- Is the program community-based or a referral center? Referral centers are beginning to train local physicians to handle preliminary workups and ovulation inductions, so that the patients need travel to the main center fewer times.
- Does the clinic offer assistance in obtaining the highest possible insurance reimbursement for the patient? What has been the reimbursement experience of other patients with similar insurance plans? Does the clinic offer a sliding fee scale for patients with low incomes?

SOURCE: Office of Technology Assessment, 1988.

DISTINGUISHING THERAPEUTIC FROM EXPERIMENTAL TREATMENTS

One difficult problem in assuring high-quality infertility treatment is that of correctly characterizing a new kind of service, such as IVF, as experimental or therapeutic. The classification has implications for whether fees may be charged, for insurance coverage, and for determining the amount of information that must be made available before a person can be considered to have made an informed choice to undergo the procedure. And any classification of IVF as "experimental" further complicates ethical questions concerning the appropriateness of experimenting with human embryos (16).

As noted earlier, ACOG classifies IVF as a "clinically applicable procedure"—i.e., no longer purely experimental (5). Similarly, a 1986 AFS position paper stated: "IVF is no longer considered to be an experimental procedure" (7). The AFS Ethics Committee, however, did not explicitly find IVF to be nonexperimental. Although it found the procedure to be ethical medical practice, it concluded that "when a procedure [like IVF] is being done for the first time by a practitioner or for the first time at a particular facility, that procedure should be viewed as experimental," adding "there is merit to the position that charges should be reduced until the clinic has established itself with a reasonable success rate" (7). This line of reasoning could be troublesome, as it is unclear whether it is the number of times a procedure has been done or the success with which it is used that determines its experimental status. Further, even an experienced practitioner might encounter reduced success upon changing laboratories or laboratory personnel.

Some might argue that a procedure is either experimental or it is not, depending on whether it is a deviation from standard medical practice for the purpose of testing a hypothesis or obtaining new knowledge. The fact that a particular person or facility is performing it for the first time does not necessarily change the nature of the procedure itself. The AFS executive board in 1986 passed a resolution calling on insurance companies to reimburse for IVF, as it is no longer an experimental procedure. Institutional Review Boards (IRBs) across the country have also struggled with this issue, some concluding that IVF is research and others that it is innovative or accepted clinical practice.

Federal regulations define "research" (rather than "experimentation") as "a systematic investigation designed to develop or contribute to generalizable knowledge" [45 CFR 46.102(e)], thus focusing on the intent of the individual performing the research. In general, before such an activity is conducted on a human subject, there must be successful animal work, a reasonable hypothesis, IRB review, and informed consent from the research subject.

Some commentators have suggested that there is no clear line between experimentation and therapy (as indeed the preceding definitions suggest), and have argued for a continuum that includes a third category of interventions between research and therapy, often designated "innovative therapy." The AFS also suggested new terminology for such categories, proposing "clinical experiment" for an innovative procedure with little or no historical record of success, and "clinical trial" for the systematic effort to improve the effectiveness of an existing procedure (7).

In a similar vein, the Blue Cross/Blue Shield Association's Technology Evaluation and Coverage (TEC) Program groups procedures, for the purpose of coverage, as experimental (largely confined to animal or laboratory research), investigative (limited human applications but lacking wide recognition as proven safe and effective), and standard (widely accepted as clinically effective, but may need to be qualified as standard only under certain specified conditions) (33).

The Food and Drug Administration (FDA), on the other hand, has not adopted these distinctions, and a drug is either "investigational" (research) or proven "safe and effective" (i.e., therapeutic). IRBs have authority to review and approve all "research" and to decide whether or not a proposed use is "research." Rulings by individual medical societies, insurance companies, or governmental agencies are not conclusive. Indeed, such rulings may often be in conflict, as they currently are in the area of heart and liver transplantation and IVF (see, e.g., 45 CFR 46).

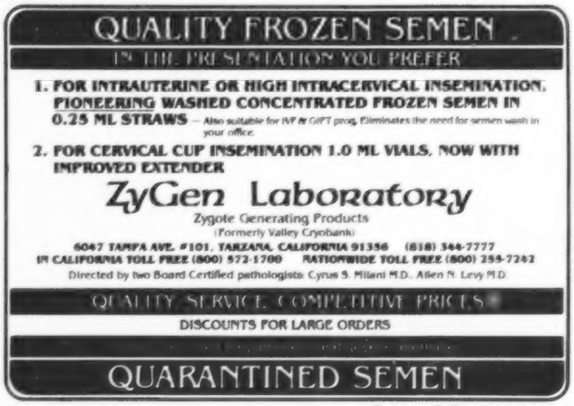
SCREENING DONOR SPERM FOR SEXUALLY TRANSMITTED DISEASE

Professional societies can also continue to work to minimize the risks associated with procedures that have long been accepted as therapeutic. One example can be drawn from the debate over the use of fresh and frozen sperm for artificial insemination by donor. Only by freezing sperm and testing the donor after 3 or more months have passed can sperm be shown to be almost incapable of transmitting the human immunodeficiency virus. This is because current laboratory tests for exposure to the virus are as yet sufficiently crude that they require 3 or more months for the concentration of antibodies to become high enough to be detected. AFS guidelines in place through

1987 did not suggest that physicians abandon the use of fresh sperm, and suggested instead that they carefully screen donors to exclude any whose exposures in the months just prior to the donation might have left them infected. OTA's national survey found that physician awareness of AFS standards was tantamount to their adoption (63). As long as there was no evidence that this practice had failed to screen out all infected donors, its possible inadequacies were theoretical only, and widespread physician preference for possibly more efficacious fresh sperm was accepted.

Just such evidence came out of Australia, where four of eight women became seropositive after insemination with sperm from a seropositive donor (50). In 1987 there were reports that at least one U.S. sperm bank found that a donor seroconverted (i.e., tested positive for HIV after having tested negative at the time of donation) during the time that his sperm where quarantined (55, 58,70). Another U.S. sperm bank, despite adherence to the 1987 AFS standards for fresh-sperm donors, subsequently found the donor to be infected and capable of having transmitted the virus at the time of donation (56,70).

In 1988, new AFS standards were developed. They stated that in light of the inability to ensure that sperm are incapable of transmitting HIV without freezing the sperm and retesting the donor, the use of fresh sperm is unwarranted (50). These new AFS standards are identical to those adopted in 1988 by the FDA, in conjunction with the Centers for Disease Control (CDC), and ACOG is expected to follow suit (70).



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Some physicians express concern that exclusive reliance on frozen sperm, which is widely perceived to be less efficacious (63), will result in a population of women who fail to achieve pregnancy at all when using donor insemination (56, 70). Another concern is that physician education will stress careful screening of donors for HIV, while failing to stress the importance of improving screening practices for more prevalent infectious diseases, such as hepatitis (56), that are also known to have been transmitted by donor insemination in the United States (64). A final concern is that formal regulation by a State or the Federal Government may prevent physicians from returning to the use of fresh sperm should convenient and economical HIV antigen tests become available, making reliable donor screening possible at the time of donation.

NONREGULATORY PROTECTION OF PATIENTS AND RESEARCH SUBJECTS

Short of regulating infertility treatment and research, the Federal Government could work to facilitate greater data collection and self-regulation. This can be done by authorizing additional Federal efforts for epidemiological studies of infertility (see chs. 1 and 3) and by encouraging the use of governmental, professional society, and insurance industry resources to hold consensus conferences and to recommend protocols for high-quality care. For example, consensus conferences could evaluate data on patients and recommend a protocol that lists the best indications for the use of IVF as opposed to GIFT. Conferences and reports could also help define a "successful" program, distinguish experimental from investigative techniques or applications of standard techniques, and make more uniform the minimum level of staffing for a program.

Concern over costly and possibly premature applications of medical innovations led to the 1977 creation of the National Institutes of Health (NIH) Consensus Development Program (49,62,66). Its purpose is to develop consensus on the clinical significance of new findings and the financial, ethical, and social impacts of a procedure's development and use. To that end, an Office of Medical Applications of Research coordinates consensus conferences and other activities with the NIH Bureaus, Institutes, and Divisions, and guides the appointment of expert advisory panels to review and make recommendations on medical innovations and their applications. Denmark, Israel, the Netherlands, Norway, Sweden, and the United Kingdom have used similar mechanisms to review medical developments (33).

Despite criticisms that the NIH consensus advisory panels have at times been biased, worked from insufficient data, or made unsupported recommendations (1,34,38,48), over 60 consensus conferences have been convened in the last decade, with noticeable effects on the practice of medicine in several areas, including indications for breast cancer screening by mammography, surgical protocols for treatment of breast cancer, and extension of Medicare and private third-party insurance coverage for liver transplantation. Little or no effect has been demonstrated, in contrast, on the practice of cervical cancer screening or rate of cesarean delivery (49), areas that were also the subject of such conferences.

One important consideration in whether an NIH consensus conference is appropriate is whether the questions concerning the medical technology are primarily scientific and clinical, or primarily ethical or economic. The conferences are more effective when they focus on the former. They are also most useful when professional consensus has not yet begun to build.

A 1987 study funded by NIH to assess the effectiveness of its consensus conference program found that all too often the conference lagged behind other professional educational activities, and so was not itself responsible for any demonstrable improvement in clinical practice. The study also demonstrated that simple dissemination of information concerning the best practice of a technique or use of a device would be insufficient unless coupled with an educational program directed at altering physician practice (39).

In addition, one Federal agency is dedicated to technology assessment of clinical medicine—the Office of Health Technology Assessment (OHTA) of the National Center for Health Services Research and Health Care Technology Assessment, under the Office of the Assistant Secretary for Health. Although much of its work is in response to requests from the Health Care Financing Administration for medical guidance prior to decisions concerning Medicare coverage, OHTA can review other technologies as well (48 FR 2444). OHTA reports focus mainly on safety, efficacy, and indications for use, but at times cover cost-benefit analyses too.

Although infertility treatments are of interest to only a small number of Medicare-eligible patients, the Prospective Payment Assessment Commission (ProPAC) could be useful in forging agreement concerning the experimental or clinical status of procedures such as IVF. It was established by the Social Security Amendments of 1983 (Public Law 98-21) as an independent, legislative-branch commission to advise and assist Congress and the Secretary of Health and Human Services to maintain and update the Medicare prospective payment system. ProPAC is required to collect and assess information on safety, efficacy, and cost-effectiveness of medical technologies in order to identify medically appropriate patterns of health resources use. Its findings influence the development of the diagnosis-related groups now used as the basis for Medicare reimbursement to hospitals.

Among professional societies, the American Medical Association (AMA) has a diagnostic and therapeutic technology assessment program, under the aegis of the AMA Council on Scientific Affairs. The program uses panels of experts to examine and report on the safety, effectiveness, and indications for emerging or new medical technologies. The American College of Physicians' Clinical Efficacy Assessment Project uses expert opinion and group judgment to provide up-to-date information and guidelines for a variety of medical and surgical procedures, with an emphasis on safety, efficacy, and cost. Procedures that have been evaluated by the program include biofeedback for hypertension and ambulatory cardiac catheterization (26).

The University of California—San Francisco is the home of the Institute for Health Policy Studies, a multidisciplinary research institute that studies efficacy and cost-effectiveness of both standard and new medical technologies. Its advice is often requested by Congress and Federal agencies such as the Federal Trade Commission (FTC) and the Department of Health and Human Services. The Institute of Medicine, an organization chartered in 1970 by the National Academy of Sciences, also has an active technology assessment group, and responds to many congressional requests for studies of the efficacy and costs of particular medical and surgical treatments.

Among industrial groups, the Blue Cross/Blue Shield Association has two influential programs that affect the degree to which certain medical procedures are recognized as necessary, safe, effective, and covered by insurance. The Medical Necessities Program focuses on identifying procedures that are not effective or not strictly necessary. The Technology Evaluation and Coverage Program develops medical policies for the Association's *Uniform Medical Policy Manual*, which is provided to all local plans. Although the manual is largely advisory, its use is required by certain national-account corporate plans that cover residents of the several States. As indicated earlier, TEC is mainly concerned with categorizing medical technologies as experimental, investigative, or standard (33). Other private, third-party payer groups with technology assessment programs include Kaiser Permanente, a California-based health maintenance organization with almost 2 million members.

STATE AUTHORITY TO REGULATE INFERTILITY TREATMENT AND RESEARCH

"Police power" is not a term referring to municipal police as much as it is a technical term that has come to refer to all the powers of government to protect the health, safety, and morals of its citizens (17,71). All the traditional powers of government, including police powers, are retained by the States, even if parallel areas of Federal authority have developed. Thus, almost all criminal laws are State laws, almost all public health measures are State measures, all licensing of medical personnel and facilities is based on State law, and almost all tort law is State-based.

Accordingly, the States have the authority to regulate noncoital reproductive techniques directly in a variety of ways. All these are limited by the provisions of the U.S. Constitution regarding the rights of individual citizens, but the State's inherent powers to protect patients, research subjects, and perhaps even embryos are broad and provide many potential avenues for regulation. Those with the most relevance to noncoital reproductive techniques are licensing of health care personnel and facilities, certificate-of-need laws, medical malpractice litigation, restrictions on the sale of embryos, and criminal statutes.

Licensing Health Care Personnel

IVF, embryo transfer, and GIFT are medical procedures requiring the skill of a licensed physician. This means that the State can and does limit the performance of these techniques to licensed physicians, and that any nonphysician performing them is practicing medicine without a license—a crime in all States. Some States have enacted statutes declaring that artificial insemination by donor is the practice of medicine, in order to limit or regularize its use. Others have passed artificial insemination laws designed to ensure the legitimacy of the resulting child (see ch. 13) but that refer only to inseminations performed by a physician, thus creating the possibility that the statutes' terms will not fully apply when artificial insemination by donor is performed without a physician's supervision (see discussion of case of *Jhordan C.* in ch. 13).

The medical justification for restricting performance of donor insemination to physicians is that they are better able to screen donors to ensure that no infectious or genetic disease is passed to the recipient or child. Other justifications include the facilitation of screening for nonmedical conditions, such as welfare dependency, marital status, or sexual orientation. It can be argued, however, that artificial insemination should not necessarily be considered the practice of medicine (36). It is easily performed by a nonphysician, requires no elaborate equipment, and may be used to overcome a social condition—lack of a male partner—rather than a medical condition. Further, physician screening against infectious and genetic disease would not be available for coital reproduction, and thus some might argue is not necessarily an appropriate subject of State law with respect to artificial insemination performed by the recipient herself.

Medical licensing protects both the public, who may be incapable of informed comparison shopping and evaluation of quality, and the profession, which otherwise might suffer from undue or unfair competition. This limitation of services to licensed physicians has at times created considerable controversy in the area of childbirth, notably concerning patients' desires to use midwives, but fewer problems regarding noncoital reproductive techniques. One problem, however, has been the inability of singles and homosexuals to locate physicians who find it ethically acceptable to assist them with IVF or artificial insemination by donor.

ACOG's 1986 Ethics Committee statement acknowledged a trend in the United States to recognize that unmarried persons can provide excellent care for their children, and called on physicians to handle requests for infertility services from these people based on the probable welfare of the child and in such a way as to avoid arbitrariness. It went on to state, however, that physicians ought to be free to accept or reject patient requests if these considerations are kept in mind (4). To the extent that physicians continue to have qualms about the appropriateness of helping singles or homosexuals to have children, as demonstrated in OTA's national survey of artificial insemination practice (63), and as long as physicians are the only persons entitled to offer these services, this problem of access will persist among unmarried and homosexual women.

Medical licenses are general licenses—i.e., once an individual graduates from an approved medical school, passes a standard examination, and does an internship or residency, he or she can be licensed to practice medicine. The practice of medicine is broadly defined, and includes diagnosis, treatment, prescription, surgery, and other specific activities as the statute or the State's board of medicine may decree.

Specialty Boards, through which a physician may become board-certified in a specialty following more years of specialty training and passing another exam (e.g., Obstetrics and Gynecology), are private certifying agencies. No State requires that a person be a board-certified obstetrician-gynecologist or a member of a private professional organization in order to provide services related to any noncoital reproductive technique. A State could, however, specify (either by statute or regulation) particular qualifications necessary for providing a specialized service, such as infertility treatment. Thus far, only Louisiana has done this, and only with respect to IVF.

On the other hand, it seems likely that at least some State licensing boards will follow the lead of the Massachusetts Board of Registration in Medicine and require its licensees to follow certain nationally recognized standards in defined specialties, such as anesthesiology. The Louisiana law fits this pattern, as it accepts compliance with the training and staffing guidelines of ACOG or AFS as sufficient to meet State law. The Federation of State Medical Boards of the United States publishes compilations of the activities of State licensing and discipline boards, so that States may compare their provisions with those of others (22).

Licensing also provides State governments with the right to intervene (at the request of a patient, another physician, or any third party) to review an individual physician's practice and to discipline the physician, by sanctions ranging from simple censure to license revocation, for failure to follow proper standards in the delivery or advertisement of medical services (22,27). Physicians who are incompetent or have been negligent on more than one occasion, for example, could have their licenses revoked (22,27). Although such disciplinary actions have historically been rare, many States are trying to improve the operations of their medical licensing agencies and to strengthen the policing function of these agencies. This mechanism is after the fact, but it might deter some unqualified physicians from claiming to be experts in infertility treatment.

Licensing Health Care Facilities

Following World War II and the passage of the Hill Burton Act of 1946 (which made hospital licensure a prerequisite to receiving Federal funds), States that did not have mandatory licensing for hospitals proceeded to adopt statutes requiring such licensure and setting forth certain minimum standards, mainly for construction (30).

Currently all 50 States and the District of Columbia require that hospitals be licensed, although the scope of the laws varies considerably (71). Traditionally, these statutes have focused on minimum safety standards concerning construction, fire, and equipment, rather than on the quality of services delivered at the facility. Nonetheless, the States do have the authority to regulate service provision. Most, however, rely on a private organization, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). In addition, DHHS has in practical effect delegated to JCAHO much of its own authority to certify facilities for Medicare reimbursement.

About half the States also license medical laboratories, and a majority regulate the qualification of laboratory personnel (53). Clear authority exists to adopt regulations governing medical laboratories. States could, for example, adopt laboratory licensing regulations aimed specifically at infertility clinics or free-standing IVF, artificial insemination, embryo transfer, or GIFT programs. On the other hand, one general exception to laboratory licensure relates to a physician's private office. States do not generally license private doctors' office procedures; they license physicians. Therefore, to the extent that a physician can offer infertility treatment in an office setting, it would be unlikely that facility licensing schemes would apply directly to the activity, although certainly it could influence office practice (23).

Health Planning and Certificate of Need

In the early 1970s, the Federal Government established two separate hospital capital expenditure programs intended to control the cost of medical care: the Section 1122 program authorized under the Social Security Act Amendments of 1972 (Public Law 92-603) and the certificate-of-need (CON) program established by the National Health Planning and Resource Development Act of 1974 (Public Law 93-641). The Section 1122 program provided for voluntary agreements between State governors and the Secretary of HHS, such that any hospital failing to obtain State approval of a capital expenditure would not be eligible for Medicare reimbursement of that capital expenditure. The 1974 legislation created a mandatory national system of State and local health planning agencies to conduct reviews of capital expenditures for construction and major equipment purchases, and to perform other review and monitoring tasks that would help reduce medical costs (57).

Some States have used their CON programs to control the introduction of expensive new medical technologies, such as heart transplants. The CON mechanism could be used for large clinics or hospitals offering IVF, embryo transfer, or GIFT, in order to ensure adequate laboratory facilities and equipment, and to determine patient need in light of the efficacy of the procedure, before extensive funds are committed. At least two university clinics and one private clinic have had to comply with CON procedures before establishing IVF facilities (7). But CON procedures are generally not applicable to small office practices, although some exception is made if the services are reviewable were they offered by a hospital or if they go beyond those generally offered in a physician's office (7,31). Further, Federal funding for CON and Section 1122 programs dropped to zero in fiscal year 1987, and the 1974 legislation was repealed in January 1987. By late 1987, only 40 States maintained either a CON or a Section 1122 program, and many States do not structure their programs to apply to nonhospital facilities (69). Of those that do, many do not review expenditures of less than $1 million, which makes their applicability to even hospital-based IVF programs somewhat doubtful.

Medical Malpractice Litigation

Tort law is a nonregulatory means for social control of risks to health and safety (10). Permitting individuals to sue those who have wronged them through negligence serves as a mechanism for financial and emotional compensation, and for quality control. Of these three, the one most relevant to noncoital reproductive techniques is quality control. Theoretically, by making people responsible for their actions, individuals have an incentive to act responsibly. In practice, medical malpractice litigation suffers from numerous shortcomings, including the fact that it focuses on past errors rather than future improvements. Nevertheless, it has had a profound effect on the practice of medicine and infertility treatment. For example, concerns over malpractice liability have altered the way physicians balance the risk of multiple births against the goal of initiating conception when fertility drugs are used to stimulate ovulation.

The medical profession largely sets its own practice standards. Accordingly, to prove medical malpractice by an infertility specialist, another infertility specialist generally must testify that what the practitioner did was not "good and accepted medical care" for the specialty, and thus amounted to a breach of the practitioner's duty to the patient. Otherwise, the plaintiff patient would need to show that the accepted medical practice in this field is itself so poor that it constitutes negligence toward the patient.

The major issue in this context is how such standards of practice are set in the treatment of infertility, particularly when treatment involves noncoital reproduction. The standard of care in medicine is generally defined by "standard medical practice"—i.e., what reasonably prudent physicians customarily do. The problem is that, at least with IVF, embryo transfer, and GIFT, these procedures are so new that no "standard" of practice exists yet, and practices actually vary widely. In addition, negligence litigation as an alternative to regulation is probably "unsuitable for deterring systems failure in cases where the system is new and is introduced into the marketplace without the realization that it is having a significant harmful effect on health, safety or the environment" (10).

ACOG and AFS have made an effort to identify good medical practice in the area of noncoital reproduction. As indicated earlier, both organizations develop and publish guidelines for practice, to be used for practicing and teaching their specialties. It is made clear, however, that these guidelines are voluntary. As ACOG states in the introduction to its published standards:

> It is important, particularly to those agencies or individuals who may consult this manual in preparing codes and regulations governing the delivery of obstetric-gynecologic health care, to recognize that the standards set down here are presented as recommendations and general guidelines rather than as a body of rigid rules. They are intended to be adapted to many different situations, taking into account the needs and resources particular to the locality, the institution or type of practice. Variation and innovation which demonstrably improve the quality of patient care are to be encouraged rather than restricted (5).

These guidelines can play a central but not determinative role in malpractice litigation. The general rule in medical malpractice litigation is that the physician must demonstrate that his or her practice conformed with that of the "reasonably prudent physician" (or specialist, if the defendant is a specialist) under the same or similar circumstances. Nonconformity is evidence of negligence. Conformity is evidence of due care, but is not an absolute defense to an assertion of negligence. Conformity to professional custom or guidelines is just one circumstance considered when assessing whether an act was negligent.

One reason compliance with such professional guidelines is not determinative is that a court may find that an entire profession or specialty has lagged behind in adopting rules required by the standard of reasonable prudence. Defendants have tried unsuccessfully to use adherence to customary standards as a conclusive defense. Over 50 years ago, Justice Holmes noted:

> In most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission (60).

Even compliance with a Federal or State statute may not be sufficient to defend fully against a claim of negligence:

> While compliance with a statutory standard is evidence of due care, it is not conclusive on the issue. Such a standard is no more than a minimum, and it does not necessarily preclude a finding that the actor was negligent in failing to take additional precautions (52).

Overall, while compliance with professional or Federal guidelines is evidence of due care, physicians must continually improve their own safety practices to be free of all charges of negligent care.

Regulating Research on Embryos

States specifically addressing IVF research, with the exception of Louisiana, have focused on monitoring and recordkeeping, rather than on limiting research. (See ch. 13 and app. C for summary of State IVF statutes.) Some fetal research statutes, however, are sufficiently ambiguous that they might apply to IVF research or at least have some chilling effect on embryo research within the affected State. (See ch. 13, table 13-2, and app. C for discussion of applicability of fetal research statutes to IVF treatment.)

The laws of Arizona, Massachusetts, Michigan, North Dakota, Ohio, and Rhode Island extend to research with "embryos," and in Kentucky, Louisiana, Missouri, Oklahoma, and Pennsylvania they apply by functional definition to any product of conception (7). Furthermore, in Maine, Massachusetts, Michigan, North Dakota, Rhode Island, and Utah the fetal research statutes are not limited to postabortion products of conception or research in connection with abortion.

Even where statutes are restricted to the products of an abortion, it is still somewhat unclear whether ova fertilized in utero by artificial insemination and then flushed from the uterus prior to implantation would be covered, and thus numerous statutes might possibly be applied to research applications.[1] The applicability, however, of all these fetal research statutes is in question in light of the 1986 case *Margaret S. v. Edwards*, which struck down for vagueness a Louisiana ban on experimentation with fetuses obtained from induced abortions (see chs. 12 and 13) (42).

Criminal Statutes

States have the authority to declare criminal, within constitutional limitations, activities dangerous to the public health, safety, welfare, or even morals. Some States, as indicated, make it a criminal offense for a nonlicensed person to offer artificial insemination by donor or outlaw certain types of fetal research. The statutes in Florida and Louisiana prohibiting the purchase and sale of human embryos are based on consideration of the fetus or embryo, as well as larger considerations of public morality and respect for the products of human conception. Criminal homicide statutes are grounded in concerns for public safety, however, and rarely apply to the destruction of embryos in vitro. Few States have extended homicide laws to include unborn children without indicating that they are referring to unborn children in utero (9). Further, in at least two States with embryo protection statutes (Massachusetts and Illinois), district attorneys have agreed not to seek to prosecute any physician engaged in IVF, whether therapeutic or research, so long as the physician agrees to attempt to implant all the embryos created by the process (see ch. 13).

FEDERAL AUTHORITY TO REGULATE INFERTILITY TREATMENT AND RESEARCH

In theory, the Federal Government can only exercise those powers specifically granted to it in the U.S. Constitution. None of those powers relates directly to medical care or to human reproduction, so all the laws on licensing health care personnel and defining family relationships are State laws, as described in the preceding section.

Yet the Federal Government is not powerless in this area. With respect to health care in general, and to noncoital reproductive techniques in particular, Congress can influence the development of medical techniques forcefully in areas where it has indirect authority to get involved. First, it can encourage nonregulatory efforts by governmental agencies, professional societies, research institutes, and industrial groups, in order to influence the clinical practice of new infertility therapies, a topic discussed at the end of this chapter. Second, the Federal Government has extensive regulatory powers over health care under its taxing and spending power and under the interstate commerce clause.

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[1] These include statutes in Arizona, Florida, Indiana, Lousiana, Maine, Massachusetts, Michigan, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, Utah, Wyoming. See app. C for summaries of State fetal research statutes' applicability to embryo research.

Taxing and Spending Authority

Article I, Section 8 of the U.S. Constitution states that "Congress shall have Power to lay and collect Taxes." This is a direct authority, and Congress may tax individuals whom it may not otherwise regulate independently. This same section also provides that Congress may spend money "for the common Defense and general Welfare of the United States." It is through the use of conditional appropriations—i.e., attaching strings to grants of money—that Congress derives its power to regulate through spending (61).

One question is whether the "general welfare" clause grants Congress authority to do whatever is in the "general welfare" of the country, or whether it is restricted to spending money. Attempts to limit the use of Federal funds to noncoercive purchases have proved ineffective, and it is generally recognized that Congress itself can decide how to spend Federal monies, limited only by the Bill of Rights and the Constitution's implicit protections of State sovereignty (29,61). There is no longer any question that:

> . . . the Federal Government, unless barred by some controlling constitutional prohibition, may impose the terms and conditions upon which its money allotments to the states shall be disbursed, and that any state law or regulation inconsistent with such Federal terms and conditions is to that extent invalid (37).

The State must, of course, comply with the Federal conditions only if it wants to receive the Federal funds (28).

Research on Human Subjects

The most important area in which Congress has used its spending power to adopt regulations related to noncoital reproductive techniques has been in the area of research on human subjects.

Current Federal regulations on research with human subjects have evolved from a combination of circumstances involving the military, the executive branch, and Congress. The key document in this brief history is the Nuremberg Code, developed by U.S. judges sitting in judgment of Nazi physicians under U.S. military authority following World War II (20). That document sets forth basic rules still in use today. It was adopted by the United Nations and the U.S. Army, but not formally used to help determine DHHS policy until the mid-1960s, when the Department's first regulations on research with humans were promulgated.

Following a series of public scandals involving unethical research, including the Tuskegee syphilis study (65) and the Jewish Chronic Disease Hospital case (32), Congress passed the National Research Award Act of 1974 (Public Law 93-348), establishing the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to study medical research settings and to recommend regulatory standards. The Commission was established within the Department of Health, Education, and Welfare (now DHHS). The Commission's activities led to the adoption of a number of regulations concerning federally funded research with human subjects.

The regulations provide that institutions receiving Federal funds (the only ones bound by the regulations) can voluntarily agree to have all of the research done on their premises or by their employees and faculty members subject to the Federal guidelines. Most institutions have agreed to be bound by Federal regulations, and have evidenced this agreement in the form of a "general assurance" given to DHHS (40).

The regulations provide that all federally funded research, except that which is specifically exempted, shall be reviewed by a local review group called an Institutional Review Board to ensure that risks to subjects are minimized, that risks are reasonable in relation to anticipated benefits, that selection of subjects is equitable, and that informed consent is obtained and properly documented.

During the National Commission's 4-year tenure it issued a number of reports, which led to DHHS adoption of a series of specific regulations applying to research "involving fetuses, pregnant women, and in vitro fertilization" (45 CFR 46.201-46.211). The National Commission limited its definition of "fetus" to a product of conception from the time of implantation, so research on extracorporeal embryos was not covered.

Because research on embryos and fetuses was seen as so difficult and divisive, the Commission recommended the establishment of an Ethics Advisory Board (EAB) within DHHS to continue to examine this area, render advice to the Secretary, and review specific proposals to fund IVF research. These recommendations were all adopted as regulations.

One commentator proposed that DHHS promulgate guidelines for the EAB to follow in considering proposals. These guidelines would contain minimum qualifications for IVF experimenters, standardize the laboratory conditions that must exist, develop safety standards for conducting human IVF experimentation, and establish when an IVF conceptus may be destroyed (8). The American Medical Association suggested establishing international and interprofessional groups to study the ethical, medical, and legal issues associated with IVF (35). The Ethics Advisory Board concluded that IVF and embryo transfer research could be acceptable from an ethical standpoint if certain stringent criteria were met (44 FR 35033) (67).

The provision that had the most profound effect on keeping the Federal Government out of funding, and thereby reviewing, IVF research was:

> No application or proposal involving human in vitro fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint [45 CFR 46.204 (D)].

In 1974, a researcher was told that his request for a $375,000 grant from the National Institutes of Health would be reviewed by the EAB. The grant application proposed to remove approximately 450 eggs from women undergoing surgery; the eggs would then be fertilized, with subsequent microbiopsy of the fertilized eggs. Thus, the embryos were not intended to mature to a live birth. The EAB approved the project provided that the fertilized eggs not be sustained beyond the stage normally associated with the completion of implantation, or no more than 2 weeks after fertilization. The application was never approved by the Secretary of Health, Education, and Welfare (41), however, and in 1980 the Ethics Advisory Board ceased to exist. Although the Secretary of HHS has the authority to waive the criteria for ethically acceptable IVF research, in part by reconvening the EAB to approve the waiver, this has never been done. Nor has a new EAB ever been appointed. The result has been an unofficial moratorium on all Federal funding and oversight of IVF research.

In 1980, pursuant to Public Law 95-622, a new Federal commission was created for 3 years by Congress—the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. It endorsed the conclusions of the EAB on IVF, but completed no further analysis on noncoital reproductive techniques (51).

The regulations on research with human subjects have also been adopted, with a few modifications, by the FDA (51 FR 20203-20208), and will likely soon be adopted by other Federal agencies involved with such research. These regulations could be important for the responsible development and early use of noncoital reproductive techniques, since they provide a principled framework within which to assess their risk/benefit ratio, to protect participants, and to ensure informed consent.

Although these regulations were employed in the initial tests of GIFT in Texas and of embryo transfer in California (13), they have generally not been used recently for IVF, on the basis that IVF is not a clinical experiment but rather a clinical practice, albeit with a developing procedure. However, no uniform protocol for IVF exists. Further, the technique never went through a formal or regulatory research stage in the United States to demonstrate either safety or efficacy, in large part due to the lack of Federal direction and Federal funding.

In 1985 Congress authorized a 12-member, bipartisan Biomedical Ethics Board consisting of six senators and six representatives (Public Law 99-158). Pursuant to the statute, the Board was named in 1986, and in 1987 began appointing a 14-member Advisory Committee composed of citizens with interest or expertise in biomedical ethics. The Board is directed to conduct studies in the area of ethics and health care, including studies on two specific topics:

- the nature, advisability, and biomedical and ethical implications of exercising any waiver of the standard of risk that is applied to all human research subjects, as defined in 45 CFR 46.102(g), when considering the conduct or support of research involving human fetuses (to be completed no later than May 20, 1988); and
- research and developments in human genetic engineering (to be completed no later than 18 months after the appointment of the Advisory Committee).

To date, the Board and its Advisory Committee have not begun to function.

During the 36 months allotted for study of fetal research protocols, the 1985 legislation repeals the Secretary of HHS's prior authority to call for a waiver of the CFR regulations governing the degree of risk to which a fetus may be subject in the course of research. Although this has been perceived by some researchers as a formalization of the moratorium on funding for IVF research, in fact it has little effect on embryo research. The CFR regulations set forth limits on the risks to which a fetus may be subjected during research, but "fetus" is carefully defined to mean "the product of conception from the time of implantation . . . until . . . expulsion or extraction" [45 CFR 46.203(b)]. This definition would exclude eggs fertilized either in vitro or in vivo if they are never implanted in a uterus.

Thus, the 1985 law does not affect the ability of the Secretary to waive the limitations on IVF research, limitations that were recommended by the EAB although never adopted into regulation. EAB approval is still required for DHHS funding of IVF research. Only a request by the Secretary of HHS to waive EAB review, coupled with a reconstitution of the EAB so that it might agree to waive its right to review, can permit funding of IVF research without Ethics Advisory Board review.

The effect of this moratorium on Federal funding of IVF research has been to eliminate the most direct line of authority by which the Federal Government can influence the development of both embryo research and infertility treatment so as to avoid unacceptable practices or inappropriate uses. It has also dramatically affected the financial ability of American researchers to pursue improvements in IVF and the development of new infertility treatments, possibly affecting in turn the development of new contraceptives based on improved understanding of the process of fertilization.

Models of Financing

Other countries that offer IVF seem to have done better at monitoring it than the United States has, probably because IVF is covered by their nationally financed health insurance plans. Through this financing power, the services are generally restricted to State-licensed clinics, and uniform guidelines for their provision can be developed and enforced. Although it seems unlikely that the United States will soon directly fund infertility services that include artificial insemination by donor, IVF, embryo transfer, and GIFT, it is useful to consider the range of regulatory authority that such funding would permit.

Direct funding would give the Federal Government the authority to determine a wide variety of requirements for the delivery of a safe and high-quality service. One model of this is DHHS's 1987 "Medicare Program Criteria for Medicare Coverage of Heart Transplants" (52 FR 10935). Among other things, it provides that to be eligible for Medicare reimbursement for heart transplantation, the facility must develop adequate patient selection criteria and patient management plans and protocols, and must have a sufficient commitment of resources, sufficient clinical expertise in related areas, adequate data maintenance, and reasonable laboratory facilities.

Most innovative, however, is the requirement that the facility have a demonstrated experience and survival rate before any procedures will be reimbursed. Tying reimbursement to actual performance could have a powerful influence on the quality of services made available to the public. Specifically, proposed regulations would require a facility to have performed a minimum number of heart transplants, with specified actuarial survival rates (52 FR 10935).

The use of appropriate success standards in IVF (standards that, of course, private insurance companies could adopt) would reduce the number of facilities eligible for reimbursement under any scheme, since some of the estimated 169 IVF and GIFT programs in this country have yet to record a birth. It should be noted, however, that such a scheme might affect the willingness of clinics to accept patients of advanced age or who have a particularly difficult prognosis, as their less successful outcomes might affect possibilities for reimbursement despite the fact that the medical care was of acceptable quality.

Aside from direct Federal funding, five States have mandated that private insurance companies cover IVF (see ch. 8). Private insurance companies are free to set their own reimbursement or coverage policies by contract. Most cover generally accepted medical procedures, but not experimental procedures. Since there is no universal definition of "experimental," coverage often varies. When a new procedure is moving from the experimental to the realm of the generally accepted practice, there is likely to be a timelag during which individual insurance companies will be making the coverage decision (47).

Indirect Financing

The Federal Government also has the power to condition the receipt of Federal funds by a State (instead of by a health care provider) on the State's taking a specific regulatory action, such as in regard to noncoital reproductive techniques. This is true even when the connection between the State program and infertility is quite attenuated. For example, when Congress enacted the Child Abuse Amendments of 1984 (Public Law 98-457) in partial response to the controversy over medical care for severely or terminally ill newborns, it specifically required States accepting funds under this act to adopt certain regulations and procedures on child abuse and neglect.

Congress could equally mandate that States receiving such funds develop specific policies with regard to monitoring noncoital reproductive techniques, under the theory that these techniques require more monitoring than others because they are designed to produce children, and that the best interests of these children require that such services be of the highest quality. This would be true even without any inference that children conceived or born by use of reproductive techniques such as IVF or surrogate motherhood are at all harmed.

Similarly, the Federal Government has the authority to condition funding of Aid to Families with Dependent Children programs or family planning agencies on adoption of stated standards relating to infertility services if these were also offered by such agencies. An analogous example is the Federal requirement regarding consent to sterilization.

Authority Over Interstate Commerce

The second major area over which Congress has wide authority to regulate noncoital reproductive techniques is through the commerce clause of Article I, Section 8, which provides the authority "To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."

Congressional authority to pass laws relating in any reasonable manner to interstate commerce is "such broad power that judicial review of the affirmative authorization for congressional action is largely a formality" (61). Most judicial review focuses instead on the intent of Congress to interpret the reach and scope of the legislation. For example, "unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the Federal-State balance" (68).

Monitoring the Use of Noncoital Reproductive Techniques

The Centers for Disease Control (CDC) may ask State departments of health to monitor artificial insemination by donor or other uses of third-party gametes for the presence of human immunodeficiency virus or antibodies, or for the presence of other communicable diseases. CDC is not a regulatory agency and has no direct authority to regulate individual physicians or State health departments. It is under the authority of the Secretary of HHS and acts under the Secretary's general statutory authority. For example, under the Public Health Services Act (42 U.S.C. 201 et seq.), the Secretary has general authority to enact regulations to prevent the spread of diseases across State or national borders. The Secretary has used this authority to limit the travel and transportation of individuals with specific communicable diseases.

In 1988, the CDC used its authority to issue guidelines for donor insemination, so that the risk of HIV transmission could be reduced (64). While not mandatory, these guidelines do set an unofficial standard of the minimum quality of care expected from physicians. The CDC may also ask for cooperation from local health departments (which do have direct "police power" regulatory authority to demand cooperation) for assistance in collecting data relevant to communicable diseases, and this request is likely to be complied with if it is reasonable (43).

Antitrust and Information Disclosure

In response to the "trusts" developed by the railroads in the late 19th century, Congress passed the Sherman Antitrust Act in 1890 (which forbade "conspiracy in restraint of trade or commerce," and made the exercise of monopoly power a felony) and, in 1914, the Clayton Act and the Federal Trade Commission Act. The Clayton Act declared illegal four specific practices (price discrimination, tying or exclusive dealings contracts, corporate mergers among competitors, and interlocking directorates among competitors). The Federal Trade Commission Act created an independent Federal administrative agency with the power to study (and later to take enforcement action against) "unfair methods of competition" and "unfair or deceptive acts" (21).

The antitrust laws have only recently been used against medical practitioners (11). Some groups, for example, charged that obstetricians in a certain area had conspired to fix prices for abortions and other services to try to eliminate these services from the marketplace (24). It is unlikely that the Antitrust Division of the Justice Department (or private individuals or corporations) will find any occasion to attack concerted action in infertility services, since these are generally run as small businesses rather than as large-scale operations. Yet the Federal Trade Commission could become involved in examining potential "unfair practices."

One of the practices FTC has found unfair is a seller's refusal to disclose information about various aspects of products (18). Examples include the failure to disclose the efficiency rating ("R value") of home insulation, the octane level in gasoline, or the drop-out and placement rates of vocational schools (18).

Analogously, FTC could find it an unfair practice for infertility clinics not to disclose their pregnancy or live-birth rates, or any other piece of information that consumers need to decide whether to attempt a pregnancy by noncoital reproduction, or whether to make the attempt at a particular clinic. Misleading advertisement of success rates could also be subject to FTC scrutiny and regulation (54). The difficulty of choosing a single method by which to calculate and advertise success rates for IVF (19,44,45), however, points up how hard it is to determine that a particular figure is misleading (see box 9-B).

Regulation of Products

The commerce power, of course, also provides specific authority to regulate articles of commerce that pass between two or more States. This authority has been used most specifically in the health care field by the establishment of FDA, which is authorized to regulate drugs and medical devices and to prohibit trade of such products in interstate commerce until they have been demonstrated safe and effective. Although this authority is extremely broad, it is of limited value with respect to noncoital reproductive techniques, since they generally do not involve the use of new drugs or medical devices, but rather of new (or

Box 9-B.—How IVF Success Rates Can Be Reported

The reporting of IVF data is limited only by one's imagination in contriving some new yardstick of performance, short of a normal liveborn child (44).

In early 1988, 41 U.S. IVF clinics reported, as a group, their success rates for 1985 and 1986 (45). These clinics represent about one-fourth of all IVF programs active in the United States and are generally the most successful. This first combined report of IVF clinics characterized the average 1986 IVF success rate as 16.9 percent (clinical pregnancy per embryo transfer cycle). ("Clinical pregnancy" denotes positive fetal heart documented by ultrasound.) This figure is one of several ways to calculate IVF success rates and may be misleadingly optimistic for some patients. It may also be inadequate to reflect success rates for procedures using frozen embryos obtained in earlier stimulation cycles.

It is important to note that regardless of how averages are expressed, they can be misleading for an individual patient. Patients who are older, who have a history of repeated miscarriages, or who have other special risk factors have smaller chances for success. Conversely, some candidates for IVF are much more likely than average to have a successful pregnancy.

Assuming an IVF candidate has passed a battery of tests determining her general appropriateness for the procedure, she's ready to start her first ovarian stimulation cycle. On average, 6 of 10 women are successful at stimulation and fertilization, leading to an embryo-transfer attempt. Following embryo transfer, the chance of becoming clinically pregnant is about **1 in 6 (16.9 percent)**, the figure highlighted in the report of the success rate of the 41 clinics. However, a woman still faces the risk—about a 1-in-3 chance—that her pregnancy is ectopic, or that it will end in a miscarriage or stillbirth. Therefore, her chance of walking out with a baby after one embryo transfer cycle is about **1 in 9 (10.7 percent)**. Calculated per stimulation cycle, a woman's chance of taking home a baby is about **1 in 16 (6.3 percent)**. She also has a 1 in 1,000 chance of winding up in the hospital due to hyperstimulation from the drugs.

On average, each patient at the 41 IVF clinics undertook 1.6 stimulation cycles, so the 1 in 16 chance of taking home a baby following one stimulation cycle can also be quoted as an overall **1 in 10 (10 percent) chance** of taking home a baby after undertaking an average course of IVF treatment.

Every couple is unique, and the chances of success may vary from the averages quoted here or by an IVF clinic. A particular patient's or clinic's past success with stimulation, egg retrieval, and fertilization may make one or another type of reported success rate more useful. Couples undertaking medically assisted conception should keep in mind that miscarriage rates are high for all pregnancies, IVF-induced or not, and that they may have to undergo many attempts before a successful pregnancy is achieved. With IVF, the odds per stimulation cycle, and even per embryo transfer, of taking home a baby are low.

Percentages mean nothing. I know, like every woman who waits in an IVF clinic, that anything less than 100% is a failure (19).

SOURCE: Office of Technology Assessment, 1988.

old) physical manipulations or surgical procedures. Unlike drugs and devices, surgical procedures and medical manipulations are not regulated by any governmental agency. Physicians are simply held to the standard of the "reasonably prudent physician" in developing and using such techniques.

The Federal Government has also used the commerce authority to require licensing of medical laboratories engaged in interstate commerce (42 U.S.C. 263). It could require Federal licensure of infertility clinics that solicit patients from out of State, although this would be more like regulating medical practice than regulating laboratory quality. On the other hand, tissue banks and other suppliers of screened gametes or even of embryos could probably be regulated in the same fashion as that used for medical laboratories or blood banks. Federal regulation to assure the safety of semen sold by sperm banks was viewed as unreasonable by only a minority of sperm banks and individual physicians surveyed in 1987 (63).

Patenting Power

The Constitution also gives Congress the explicit authority to set up a system of patents and copyrights. Historically, while drugs and medical devices have been routinely patented, it is exceedingly rare for physicians to attempt to patent surgical or medical procedures. Examples of when they have done so include a "method and apparatus for direct electrical injection of gold ions into tissue such as bone," "cranial insertion of surgical needle utilizing computer-assisted tomography," a "method for maintaining the reduction of a sliding esophageal hiatal hernia," and a "surgical method of fixation of artificial eye lenses."

Nevertheless, one venture capital corporation interested in providing embryo lavage and transfer services nationwide did apply for a patent on the process of lavage and fertilized ovum retrieval. That application is pending, along with four other related patent requests for the devices used (25). Although interest in the procedure has waned due to its low success rate relative to alternative procedures (14,15), the company has nonetheless begun to open offices around the United States and in Italy (25).

The U.S. Patent Office can no doubt issue process patents if it so chooses. The real debate over the embryo lavage and transfer patent is whether it should have been applied for in the first place, and, if it is granted, how it could be enforced. One argument in favor of allowing the patent is that its holder can enforce high medical standards by training and monitoring those who purchase licenses to use the patented procedure. Balanced against this is the tendency of a patent holder to keep unfavorable results secret, so that unbiased groups may not have an opportunity to confirm or deny claims made for the process; the inhibition by the patent of the generalized training of medical professionals; and the general inhibition against sharing scientific knowledge. Human reproduction also does not easily lend itself to patent infringement enforcement methods, and patenting new reproductive technologies remains problematic (7).

SUMMARY AND CONCLUSIONS

Professional societies such as the American Association of Tissue Banks, the American College of Obstetricians and Gynecologists, and the American Fertility Society have made efforts to regularize the practice of medically assisted conception by offering guidelines on gamete and participant screening, physician training, and clinic staffing. The Federal Government, too, has been active with regard to donor insemination. These efforts, however, may be insufficient. First, as compliance is entirely voluntary, public health hazards—e.g., human immunodeficiency virus transmission by fresh semen—may persist in medical practice, with only the threat of malpractice litigation to act as a check. Perhaps more important, many of the questions surrounding noncoital reproduction, such as recordkeeping or screening of participants who intend to raise the child or contribute to its conception, are really questions of public policy as much as of medical practice. As such, the influence of infertile couples, potential gamete donors or surrogates, social workers, attorneys, business people, and government officials on the development of regulations is appropriate.

The regulation of noncoital reproductive techniques has traditionally been primarily a matter for individual States. Just as they have regulated adoption, custody, marriage, medical licensing, and medical practice, States will bear the responsibility for regulating the noncoital reproductive techniques insofar as they are medical procedures performed by physicians. In this regard, regulations in the area of quality control and monitoring, safety, recordkeeping, inspection and licensing, consent, and requirements for donor screening are all well within traditional State activities and regulation. In extreme cases, such as banning the sale of human embryos or experimenting with human embryos, statutes would have to be carefully drawn to avoid being struck down for vagueness, as well as based on a reasonable State policy designed to protect the common good.

Federal activity in noncoital reproductive techniques, on the other hand, has been largely restricted to setting up and financing national commissions and groups of various kinds to study the scientific, legal, and ethical issues involved and to make recommendations on the actions of private and governmental organizations. The Federal Government could, however, become involved in other areas it traditionally enters, such as regulating interstate commerce, forbidding the sale of human organs, regulating false and deceptive advertising, and promulgating special rules for publicly supported human research. It could also facilitate nonregulatory efforts to establish more uniform protocols for selecting patients, choosing therapies, and defining successful outcomes. Finally, it could continue its efforts to minimize the risks associated with even the most standard therapies.

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Chapter 10

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Chapter 10

Reproductive Health of Veterans

The largest health care delivery system in the Nation, the Veterans' Administration (VA), currently offers only limited treatment for infertility in its 172 medical centers and 227 outpatient clinics. Discussions both inside and outside the VA have focused on whether the inability to reproduce is a medical disability that should be treated by Veterans' Administration facilities with available medical technologies.

Are medical treatments for infertility technological luxuries, or are they part of a comprehensive system of health care, in keeping with the goals and mission of the Veterans' Administration? Since infertility treatment often involves the examination and treatment of both partners, should the VA have authority to administer medical treatment to the nonveteran spouse? This chapter addresses some of the issues related to the reproductive health of veterans.

POPULATION OF VETERANS

There were nearly 28 million veterans living in the United States and Puerto Rico in 1985. The group ranges in age from Spanish American War veterans to some of the most recent veterans of the Nation's Volunteer Armed Services (fewer than 500 veterans under 20 years of age). In 1985, the veteran population declined by 177,000, as many more veterans died than were separated from the armed forces. Veteran deaths numbered 413,000 during fiscal year 1985, while net separations from the armed forces totaled 236,000. The total number of veterans is expected to continue declining in the absence of any major military personnel buildup. Approximately two of every five living veterans are from the World War II era (37 percent), with Vietnam era veterans constituting the second largest group (about 30 percent).

The median age of veterans in civilian life in 1985 was 52.9 years. This figure is likely to rise over the next two decades as a large number of World War II veterans reach 65. Veterans under the age of 45 constituted 35 percent of the total. Although the vast majority of veterans are male, there is a growing population of female veterans.

Male

In 1985, an estimated 26,671,000 male veterans constituted about 96 percent of the total veteran population. Their median age was 52.9 years, with approximately 35 percent being under 45 and an additional 20 percent being in the 45 to 54 age group. Although male fertility may continue beyond age 54, this age is commonly used as an upper limit after which fertility is no longer a major concern for the vast majority of men. An estimated 79 percent of male veterans are married (21). If the incidence of infertility in the general population (8.5 percent of married couples 15 to 44 years old, see ch. 3) applies to a similar age group in the veteran population, then at least 627,000 male veterans between 18 and 44 may be part of an infertile couple.[1]

This estimate makes no distinction between service-connected and non-service-connected conditions that may contribute to the infertility. However, in 1985 approximately 16,000 male veterans under the age of 55 were on VA records with known service-connected medical conditions (rated at greater than 0-percent disability) that could cause infertility (see figure 10-1). The determination of service-connected conditions is discussed later in this chapter.

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[1] This figure likely underestimates the number of male veterans with infertility problems since no data are available on the incidence of infertility for males 45 to 54 years old. However, if a similar incidence of infertility does exist in the 45- to 54-age group, then an estimated 985,000 male veterans under 55 may be part of an infertile couple.

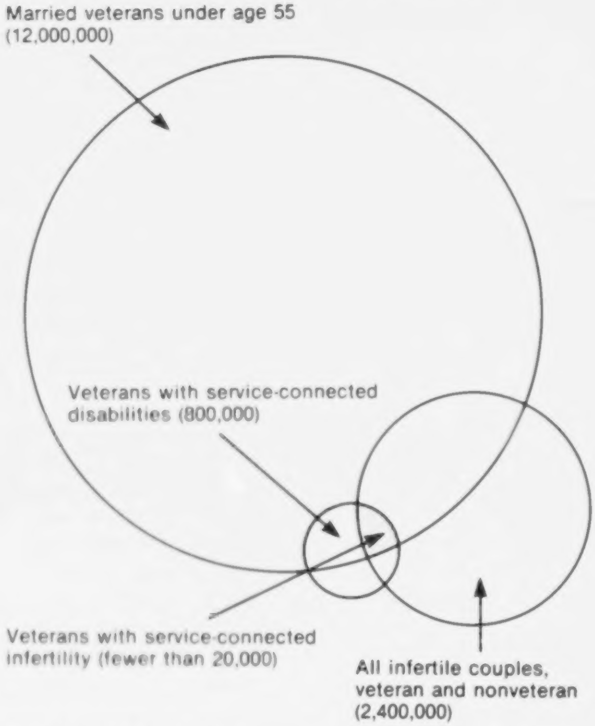
Female

The population of women veterans increased by about 15,000 between 1983 and 1985. Today, women constitute approximately 10 percent of active military personnel (21).

The majority of women veterans are comparatively young. In 1985, of the estimated 1,168,000 female veterans, approximately 54 percent were under 55 years of age. Some 42 percent were under the age of 45. Therefore, there were 490,560 women veterans 17 to 44 years of age (20,21), roughly the group of women who would most likely use and benefit from the treatment of infertility. In this group, approximately 70 percent (343,392) were married.

If the incidence of infertility in the general population is also applicable to the married female veteran population, then more than 29,000 women veterans were or are currently having problems conceiving a child. These figures approximate the total number of female veterans with possible infertility problems and make no distinction between service-connected and non-service-connected disabilities or conditions. Data recently compiled by the VA indicate that the number of known female veterans with service-connected medical conditions that would result in infertility is actually much smaller: In 1985, between 1,200 and 1,300 female veterans on VA records had a service-connected medical condition (rated above 0-percent disability) that could contribute to infertility.

Figure 10-1.—Population of Veterans With Service-Connected Conditions Related to Infertility: Comparison With Other Populations


Married veterans under age 55 (12,000,000)
Veterans with service-connected disabilities (800,000)
Veterans with service-connected infertility (fewer than 20,000)
All infertile couples, veteran and nonveteran (2,400,000)

SOURCE: Office of Technology Assessment, 1988.

FACTORS CONTRIBUTING TO INFERTILITY

General

Historically, infertility was thought to be a dysfunction of the female reproductive system. Today, male factors are believed to be the major reason for infertility in 20 to 40 percent of all infertile couples and to contribute to infertility in another 20 percent. Since infertility problems of men have not been studied as extensively as those of women, much less is currently known about the factors leading to and treatment of infertility in males.

Male infertility may be broken down into two broad categories: defects in spermatogenesis (the production of viable sperm) and semen production, and defects in the transmission of sperm from the testes to the female reproductive tract.

Table 10-1 lists a breakdown of the population of male veterans on VA records with service-connected medical disabilities that can contribute to infertility (data from 1985).

Female factors are believed to account for, or contribute to, 50 percent of all infertility among couples. These factors are classified in at least three broad categories: defects in ovum (egg) production, tubal defects (transport), and implantation problems.

Table 10-1.—Service-Connected Conditions Related to Infertility

Condition	Number of veterans
Male veterans:	
Stricture of the urethra	2,459
Removal of the penis	68
Deformity of the penis	436
Complete atrophy of the testes	2,414
Removal of testes	6,268
Partial or complete removal of prostate	2,546
Spinal cord injury	1,660
Spinal cord disease	*
Other	*
Total	15,851
Female veterans:	
Inflammation of the cervix	283
Inflammation of the uterus	65
Inflammation of the uterine tubes	151
Removal of the ovaries	664
Atrophy of both ovaries	6
Pituitary condition	67
Other	*
Total	1,236

*Estimates unavailable.

SOURCE: U.S. Veterans' Administration, Department of Medicine and Surgery, White Paper, *Infertility* (Washington, DC: 1985).

Table 10-1 lists a breakdown of the population of female veterans on VA records with a medical disability that can result in infertility (data from 1985). The incidence of infertility associated with many of these pathological conditions is most likely similar in both the veteran and nonveteran populations. However, veterans may suffer from a subset of these conditions that occur more frequently among veterans or are of special concern to the VA medical centers.

It must be emphasized that these numbers are crude estimates of the population of veterans with service-connected disabilities that could result in infertility. It is not currently known how many male and female veterans with these or other service-connected disabilities actually suffer from infertility.

Special Considerations

Post-Traumatic Stress Disorder

Some veterans of the Vietnam era suffer from a severe psychological disturbance known as post-traumatic stress disorder (PTSD), which in some instances can impair procreative ability. This may be of particular importance to male veterans who suffer from psychogenic impotence or other sexual dysfunction as a result of PTSD. Although this form of sexual dysfunction can occasionally occur in otherwise healthy men for a variety of reasons related to stress, anxiety, and emotional disorders, impotence is more notably associated with physical causes such as normal aging, vascular disease, drugs, alcoholism, and diabetes. In the general population, impotence is not considered a major factor contributing to infertility (see ch. 4), since most of the men affected are over 50 years old.

Few data are available on the actual incidence of PTSD-induced sexual dysfunction in veterans. However, since the VA already has in place special programs to meet the medical and psychological needs of PTSD sufferers (6), adequate treatment of PTSD-induced infertility may already be available. In addition, as would be true in any infertility medical practice, experts would question the advisability of providing medical assistance for procreation to any individuals suffering from a potentially severe psychological condition such as PTSD without prior or concurrent treatment of the psychological disorder.

Agent Orange

Agent Orange is of particular concern to the Veterans' Administration and to Vietnam era veterans. The effects of exposure to herbicides such as Agent Orange on the general and reproductive health of veterans and their offspring have been the focus of considerable discussion and debate (7). Studies to date have failed to document definitive adverse reproductive effects in humans from occupational exposure to Agent Orange or its components.

Many veterans and veterans' groups have suggested that exposure to Agent Orange and other herbicides used in Vietnam has resulted in a variety of deleterious health effects, including birth defects in offspring and impaired reproductive function. One study of Vietnam veterans who were exposed to Agent Orange during shipping, handling, and loading of herbicides on aircraft; spray missions; and cleaning of airplanes and equipment found no significant adverse effects on fertility (9). In the same study, an excess of minor birth defects, such as moles, was found among offspring of exposed personnel compared with offspring of nonexposed personnel.

A study based on the experiences of parents of babies born in metropolitan Atlanta from 1968 to 1980 contained no evidence to indicate that Vietnam veterans have been at greater risk than other men for fathering babies with birth defects, when all types of serious structural birth defects are combined (5). The Centers for Disease Control have been conducting additional studies of the health effects associated with Agent Orange exposure. It is currently unclear whether these studies will continue.

Because of the extensive publicity that this topic has received, many Vietnam veterans still in their reproductive lifespan remain concerned about the chance of birth defects in their offspring. Within this large group, some veterans may be reluctant to produce offspring because of previous known or even suspected exposure to Agent Orange. Although the scientific data do not support their concern, this may not mitigate the worries of individual veterans about possible serious birth defects of their offspring.

To what extent will the concerns of these veterans affect their procreative desires and ability? In view of the lack of overwhelming corroborating or contradicting data on possible birth defects resulting from Agent Orange, alternative reproductive methods such as artificial insemination by donor or ovum donation could be made available to these veterans. On the other hand, in the absence of definitive data linking Agent Orange exposure and reproductive and birth defects, is providing infertility services on this basis really warranted? Although the majority of Vietnam veterans have already had children, approximately 15 to 20 years remain in the normal reproductive lifespan of the youngest members of this group, who may only now be considering having a child or additional children.

Radiation

Exposure to ionizing radiation can lead to infertility (18). Between 1945 and 1963, the U.S. Government exploded approximately 235 nuclear devices in the atmosphere over the American Southwest and the Pacific Ocean. The Department of Defense estimates that approximately 222,000 military personnel participated in those tests. A number of veterans present at the test sites have reported either sterility or low sperm count to the National Association of Radiation Survivors, an organization that compiles data on primary illnesses of participants at nuclear test sites (15). Most of these veterans are beyond the age at which infertility is a major concern. However, since the last atmospheric tests were conducted in 1963 it is possible that a small population of veterans under 55 have radiation-induced or -aggravated infertility and wish to have children.

INFERTILITY TREATMENT BY THE VETERANS' ADMINISTRATION

At the moment, most VA medical facilities provide only limited treatments that could be considered as infertility services. Since the agency does not classify infertility as a primary disability, the VA is of the opinion that it does not have statutory authorization to perform artificial insemination or in vitro fertilization (IVF) (19). The medical treatment that is or can be provided by the VA may involve relatively simple procedures such as sperm counts, hormone measurements, and drug administration. However, even these simple procedures can be provided only in connection with the treatment of an underlying disability. The actual extent of treatment may vary widely from facility to facility, depending on the expertise of the medical staff. In fiscal year 1985, VA medical facilities recorded a total of 2,475 medical and surgical procedures that could have been associated with infertility treatment (see table 10-2).

It is clear from table 10-2 that some procedures associated with infertility are being performed in VA medical facilities. According to these data, however, surgical procedures most commonly associated with infertility treatment—e.g., repair of fallopian tubes and repair of vas deferens and epididymis—were not performed in any VA medical facility in fiscal year 1985. In addition, it is clear that little, if any, infertility treatment for

Table 10-2.—Infertility-Related Procedures Performed by the Veterans' Administration[a]

Procedure	Number of cases
Male veterans:	
Excision of hydrocele	230
Excision of varicocele	758
Repair of spermatic cord and epididymis	0
Repair of vas deferens and epididymis	0
External penile prostheses	19
Internal penile prostheses	1,468
Female veterans:	
Wedge resection of the ovary	1
Repair of fallopian tubes	0
Insufflation of fallopian tubes	0
Artificial insemination	0
Total	2,476

[a] This list does not account for all medical procedures that are associated with infertility treatment that may have been administered in VA medical facilities in 1985. In addition, neither the age of these patients nor their eligibility status (service-connected or non-service-connected condition) is considered in this list. Age is particularly important in cases of internal penile prostheses, since older men are the most likely candidates for this procedure.

SOURCE: U.S. Veterans' Administration, Department of Medicine and Surgery, Pulmonary and Infectious Disease Program, Washington, DC, personal communication, 1987.

female veterans is currently done in VA facilities. However, these numbers do not take into account the medical treatments provided for veterans by outside health care facilities and by professionals under contract with the VA. For example, many VA facilities do not provide in-house gynecological health care for female veterans. These services may be provided by local facilities or gynecologists who are under contract with the VA. Therefore, it is possible that some infertility services related to gynecological health care are being provided for female veterans in this manner.

Some additional information is available that pertains to treatment of one subpopulation of infertile veterans, spinal cord injury patients. The outlook for fertility in paraplegic men after spinal cord injury is poor; the outlook for paraplegic women is often better. These paralyzed men often (but not always) suffer from impotence because of neurological deficits in the spinal cord. The impairment in reproductive function depends on the level of the spinal cord that is damaged and the severity of the injury. The level of the spinal cord lesion is important in determining the sexual sequelae. From a practical standpoint, erections sufficient for intercourse can be achieved by less than 25 percent of spinal cord injured males. Likewise, the ability to ejaculate normally is retained by less than 10 percent of these individuals (3).

Compounding problems of impotence and ejaculatory dysfunction, paraplegics with prolonged intermittent or continuous catheterization-related prostatitis, epididymitis, and epididymo-orchitis can frequently develop obstructive lesions of the reproductive tract and damage to the testes. In addition, spermatogenesis can be severely impaired in many paraplegics and in most cases is at least reduced. The reasons for this reduction in sperm production are unclear, but increased scrotal temperature and recurring reproductive tract infections may be contributing factors. However, if there are functional testes with some ongoing testosterone production and spermatogenesis, the major problem in procreating reproducing becomes transmission of sperm to the female reproductive tract.

Several VA Spinal Cord Injury Centers (there are 20 in the United States) have been conducting research and some clinical trials on vibrational and electrical induction of ejaculation of paraplegics during infertility treatment (see box 10-A). The West Roxbury (MA) VA Spinal Cord Injury Program is conducting research on the use of electroejaculation and vibration-induced ejaculation to treat the sexual dysfunction and resulting infertility of paralyzed veterans. Although this program is in its formative stage, it has been successful in inducing ejaculation in a number of spinal cord injury patients. In addition, the program is conducting tests of the pharmacological treatment of impotence.

Another program, at the Palo Alto (CA) VA Medical Center, has had some success with electroejaculation of paralyzed veterans as well. The Spinal Cord Injury Center there has reported a live birth as a result of electroejaculation of a paralyzed veteran, sperm washing, and subsequent artificial insemination of the veteran's wife. (The artificial insemination was performed in collaboration with a private gynecologist, since the VA is not authorized to perform this procedure.) Pregnancies and live births to wives of paraplegics have been reported using these and alternative techniques in other, non-VA medical centers (1,2,3).

Box 10-A.—Obtaining Semen From the Spinal Cord Injured

Although sperm may be decreased in number and quality in paraplegics, there can be sufficient amounts to achieve pregnancy by normal or medically assisted means. A number of techniques can be used to obtain semen from spinal cord injury patients, although this area of research is in its infancy.

Intrathecal neostigmine injection has largely been abandoned because of the risks and the report of at least one death resulting from this procedure. However, this approach for inducing ejaculation, which uses injection of a pharmacologically active substance into the nervous system, has yielded several pregnancies (3).

Electroejaculation has been used in farm animals for many years and was first applied to paraplegic men in 1948. This involves electrical stimulation of the nerve complex that controls ejaculation. This stimulation is applied via electrodes placed in the patient's rectum with a device similar to those shown in figure 10-2. A number of pregnancies have been reported using this approach (1,3).

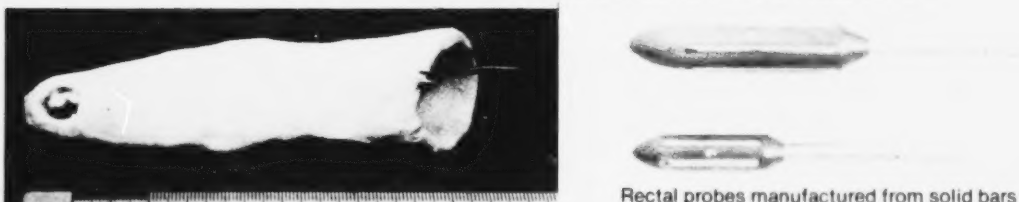
Vibratory-induced ejaculation has also been used successfully in spinal cord injury patients, although its applications are more restricted than electroejaculation. Direct application of vibratory stimulation to the penis of paraplegic men can elicit reflex erection and ejaculation. However, depending on the time since injury and the level and severity of the spinal cord lesion, electroejaculation may be the method of choice.

In a few patients, **radio wave-activated nerve stimulators** have been implanted in the abdomen around the hypogastric plexus, a nerve complex involved in reproductive function. When patients apply a suitable radio transmitter over the implanted receiver, electrical impulses stimulate ejaculation (3).

Several other approaches have been used to collect semen from spinal cord injury patients. The use of **semen capsules** (cannulae implanted into the vas deferens) to collect semen in a reservoir fashion has been reported (3). Recently, a pregnancy has been reported in a couple with a male partner paraplegic following **direct aspiration of sperm from the vas deferens combined with intrauterine insemination** (2).

SOURCE: Office of Technology Assessment, 1988.

Figure 10-2.—Devices Used in Electroejaculation Procedures



Hollow rectal probes constructed of silicone rubber reinforced with nylon mesh. Electrodes (metallic circle) are made of silver and connected to stimulator.

Rectal probes manufactured from solid bars of polyvinyl chloride. Unlike hollow probes, these devices have built-in temperature sensors that are connected to a monitor.

SOURCES: G.S. Brindley, "Sexual and Reproductive Problems of Paraplegic Men," *Oxford Reviews of Reproductive Biology*, vol. 8 (Oxford, U.K.: Clarendon Press, 1986); and C.J. Bennett, J.W.T. Ayers, J.F. Randolph, et al., "Electroejaculation of Paraplegic Males Followed by Pregnancies," *Fertility and Sterility* 48:1070-1072, 1987.

VETERANS' ELIGIBILITY FOR HEALTH CARE

General

Title 38 U.S.C., Sections 601, 603, 610, 612, and 620, define eligibility of veterans for hospital, nursing home, domiciliary, and medical care by the VA. As a result of legislation enacted in 1986 (Public Law 99-272), three different categories of eligibility for veterans' health care now exist.

Veterans in the first category must be provided hospital care by the VA and may be provided nursing home care, within the resources Congress appropriates. This group includes service-connected disabled veterans, veterans exposed to Agent Orange or radiation, former prisoners of war, pre-World War II veterans, and veterans unable to pay for medical care. To qualify for care on grounds of inability to pay, a veteran with no dependents must have an annual income under $15,000, or under $18,000 with one dependent. Veterans receiving pensions or eligible for Medicaid are automatically considered unable to pay (22).

Veterans in the second category will receive hospitalization and other medical care to the extent resources and facilities are available. This group includes veterans seeking medical treatment for non-service-connected disabilities who do not fall into any of the groups in the first category and whose incomes do not exceed the $15,000/$18,000 thresholds. If their incomes are below $20,000 (in the case of veterans with no dependents), or $25,000 (with one dependent), the medical care will be free. If their income is higher, then the veterans fall into the third category of eligibility.

The third group of veterans is expected to pay for some of their care, by making copayments or covering all the cost, including the cost of nursing home and outpatient care. In addition, the VA now has authority to obtain reimbursement from a veteran's health insurance plan for health care provided in VA facilities. However, both the copayments and any reimbursement from health insurers go directly to the U.S. Treasury and not into the VA operating budget. With the enactment of the copayment policy and reimbursement of the U.S. Treasury from private health insurance companies, it might be more feasible to provide infertility services for infertile veterans. It should be pointed out that, at this time, most health insurers do not cover infertility services such as IVF. However, other infertility services such as hormone treatment, laboratory tests, semen analysis, and ovulation monitoring may be covered by such providers. The costs associated with these latter procedures constitute a significant portion of all infertility treatment expenses (see ch. 8).

Outpatient Care

The policies just discussed deal mainly with inpatient health care. The eligibility for outpatient care is not the same. Overall, most veterans are not eligible for comprehensive outpatient care, but are generally eligible only for care to obviate a need for hospitalization (i.e., acute care) or to continue care begun on an inpatient basis. There is no requirement, as there is for veterans in the first category needing hospital care, that outpatient care be furnished to any particular veteran (Title 38 U.S.C., Sec. 612).

In some geographical locations, such as the Sun Belt States, home to a larger population of older veterans requiring medical care, availability of outpatient medical treatment for non-service-connected disabilities is limited. Nevertheless, the VA currently provides a significant amount of outpatient care for many veterans. This is of particular relevance to infertility services because as various infertility treatment methods become more sophisticated they may be routinely performed on an outpatient basis. This trend should be considered when evaluating statute changes.

Disabilities

Title 38 U.S.C., Section 601.1, defines disability as "a disease, injury, or other physical or mental defect." Further classification of various disabilities for purposes of compensation by the VA are outlined in the Code of Federal Regulations, Title 38, Part 4. Although a number of medical conditions associated with infertility are classified as disabilities, the resulting infertility is not. It is because of this determination that the VA believes it does not have the legal authority to provide infertility treatments such as artificial insemination or IVF.

Service-Connected Determination

Service-connected determination is given to any injury or disease incurred or aggregated during active wartime or peacetime service. Veterans must have been discharged or separated from the service under other than dishonorable conditions. To receive medical care for the condition, it must be rated as a disability by the VA. This has posed a problem for veterans who have service-related conditions that result in impaired fertility, since infertility per se is not considered a medical disability and therefore does not qualify for compensation. Although infertility is not a compensable disability, the underlying injury or disease that actually causes the infertility may qualify as a disability.

The determination of service connection, however, is not always clear. Because of the lack of data on male reproductive physiology, it can be extremely difficult to diagnose male infertility as the reason a couple is unable to conceive, let alone to determine the factors contributing to this condition. At present, the most common diagnosis for male factor infertility is idiopathic—i.e., of unknown cause (see chs. 4 and 6).

Although this lack of knowledge about male infertility can make attributing a low sperm count to a specific service-related event difficult, there are a few instances that can be more easily identified. For example, infertility or sterility can result from orchitis (testicular inflammation) resulting from mumps (especially in adulthood). If this infection was contracted while in active military service and subsequent male infertility is diagnosed (decreased sperm number or motility, or decreased testosterone production), service-connected designation can be made with confidence. For an individual with similar symptoms and a service record of exposure to relatively low levels of ionizing radiation, on the other hand, the determination is far from clear. Although radiation in large amounts can clearly impair testicular function and fertility, the effects of low levels are controversial and not well understood (18).

A similar but somewhat less problematic situation exists for service-connected designation of female infertility. Female infertility problems can more often be readily ascribed to a particular condition such as blocked or scarred fallopian tubes resulting from pelvic inflammatory disease. However, here too uncertainty about cause and effect occurs.

Because of the lack of knowledge about all possible factors contributing to infertility in men and women, many determinations of service connection will remain problematic. Evaluation of service connection or aggravation is best made on a case-by-case basis by physicians trained in infertility.

Compensation

Compensation for service-connected disabilities amounts to monthly financial payments if the rating of the disability, as determined by the local rating boards, is judged greater than 0 percent. In 1987, compensation ranged from $69 per month for a 10-percent rating to $1,355 per month for a total (100-percent) disability rating. Adjustments to these figures may be made, depending on number of dependents and circumstances.

COSTS OF INFERTILITY SERVICES

As described in detail elsewhere in this assessment (see ch. 8), the costs of infertility services vary considerably depending on the factors leading to the infertility and the types of diagnostics and treatments required. OTA estimates that the costs of infertility services for couples in the general population can range from $2,000 to more than $22,000, depending on the severity of the problem. In 1986 an estimated $1 billion was spent on infertility-related services. If the VA were to provide medical treatments to overcome infertility, how much would it cost?

The VA has estimated the cost of providing "services to achieve pregnancy in a veteran, or a veteran's spouse, if necessary to overcome a service-connected disability which impairs the veteran's procreative ability" to be $580,000 in the first fiscal year and $4.1 million over five fiscal years (8). However, at least one veterans' advocacy group questions the accuracy of these numbers (11).

Although OTA has estimated the costs of infertility services for couples in the general population, any accurate estimate of possible costs to the VA of providing infertility services will remain elusive until criteria are established for the following variables:

- What population of veterans would be eligible for infertility services? Those with service-connected conditions only? Which service-connected conditions would be excluded?
- How many eligible veterans actually would seek infertility treatments? In 1982, in the general population only about 55 percent of the identified infertile couples reported they wanted to have a baby. Only about one-third of the infertile couple population actually sought out infertility treatment (see ch. 3). Would the same percentages hold for infertile veterans?
- What types of infertility services would be provided? All? Would reproductive technologies such as IVF and gamete intrafallopian transfer be excluded?
- Would treatments be limited to the veteran partner of an infertile couple or include the nonveteran spouse as well? This would not only change the number of patients undergoing infertility treatment but would also significantly affect the kinds of treatments available.
- Where would infertility treatments be located? If the VA elects to provide all infertility treatments in-house, then considerable startup and maintenance costs would result. On the other hand, providing services on a contract or one-time grant basis would cost considerably less.

VETERANS' ADVOCACY GROUPS

The Paralyzed Veterans of America (PVA) is a national, nonprofit service organization for paralyzed veterans founded in 1946 and chartered by Congress in 1971. PVA has a membership of approximately 14,000 and is an advocate for 25,000 paralyzed American veterans, an estimated 175,000 nonveteran paralyzed Americans, and all U.S. veterans.

Of particular interest to PVA are veterans with service-connected spinal cord injuries or diseases. This group, estimated by the VA at approximately 1,660 (though a somewhat higher estimate is suggested by PVA), can suffer from infertility problems due to neurological deficits that result in impotence and low sperm count and motility. The PVA advocates the amendment of 38 U.S.C. to provide medical care and treatment for secondary disabilities and functional impairments resulting from primary disabilities (13). This would presumably cover treatment of infertility with procedures such as artificial insemination, IVF, and gamete intrafallopian transfer.

In addition to the issue of infertility treatment, PVA believes that specific changes in Title 38 should be made to cover not only currently available medical and surgical treatments for infertility, but other emerging technologies as well, as they become available.

Another veterans' group that has been an active advocate on this issue is the Vietnam Veterans of America. This organization recently represented an infertile female veteran in a claim against the VA. In this case, the female veteran from California petitioned the VA to pay for IVF to overcome her infertility, which was the consequence of a service-connected medical condition. After the VA denied this request, a tort claim against the VA was filed. A cash sum for IVF was awarded to the woman (17).

Amendment of 38 U.S.C. to allow the VA to provide medical services to overcome service-connected disabilities affecting procreation is also supported by the Veterans of Foreign Wars of the United States, which feels that such a program is long overdue (4). Other veterans' groups supporting such a change include the American Legion and the American Veterans of WWII, Korea, and Vietnam (AMVETS) (10,14).

Although many of these groups support amendment of 38 U.S.C. to allow procreative services, at least one veterans' group stated that "it was more concerned with possible erosion of medical benefits for our Nation's veterans than for the expansion of experimental medical treatments" (12).

ADDITIONAL VA CONSIDERATIONS

Several additional considerations are related to veterans and the VA. First, the VA's responsibility is unclear in the event of complications from infertility treatments. Who would be responsible, for example, if there were a complicated pregnancy following infertility treatments? The VA currently contracts out care for complicated pregnancies, since normal, uncomplicated pregnancies are not considered disabilities. Since the VA does not provide in-house obstetric services in most of its facilities, this issue would have to be resolved.

In addition, there is the question of responsibility in the event of an offspring with birth defects. Title 38 U.S.C., Section 351, requires that a medical condition or complication that results from medical treatment provided by the VA will itself be treated as a medical disability by the VA and render the VA fully liable for any medical malpractice claims. This may make the VA responsible for the medical care of the female partner during and after pregnancy as well as the resulting offspring. This would be the case only if the VA medical staff provided treatment within VA facilities. Such liability for birth defects or malpractice is passed on to the contractor in instances where particular medical treatments are provided on a fee-for-service basis by non-VA personnel (16). The potential for liability may be an important consideration in thinking about enlarging the VA's role in providing infertility treatment.

It should also be noted that at least two other federally sponsored programs currently cover some infertility services. Both the Civilian Health and Medical Program of the Uniform Services and Medicaid currently provide some types of reimbursement for infertility services (see ch. 8).

Other ethical and legal questions concerning the access and delivery of various infertility treatments are considered elsewhere in this report (see chs. 9, 11, 12, and 13).

SUMMARY AND CONCLUSIONS

Nearly 28 million veterans live in the United States. The overwhelming majority (96 percent) are male, 55 percent of whom are below the age of 55. Female veterans are disproportionately younger than male veterans; 490,560 female veterans are between ages 17 and 44. The number of male veterans is decreasing, while the number of female veterans is increasing.

The Veterans' Administration offers only limited treatment for infertility in its 172 medical centers and 227 outpatient clinics. Since infertility treatment often involves the examination and treatment of both partners, and the VA has authority to administer medical treatment solely to veterans, the VA lacks authority to treat a nonveteran spouse of an infertile couple. Most important, the VA does not classify infertility as a primary disability, thus severely limiting the treatment available to veterans.

In 1985, about 16,000 male veterans and more than 1,200 female veterans had known service-connected medical conditions that could contribute to infertility. Among the men, the conditions ranged from removal of the testes or prostate to spinal cord injury. Among the women, the conditions ranged from removal of the ovaries to inflammation of the fallopian tubes or cervix.

Spinal cord injury is of special concern both to the VA (which supports 20 spinal cord injury centers) and to veterans' advocacy groups. The outlook for fertility after spinal cord injury in paraplegic men (although not women) is often poor. Erection and ejaculatory dysfunction, compounded by infections of the reproductive tract, are common. Research at VA spinal cord injury centers on the use of electroejaculation and vibration-induced ejaculation is likely to offer hope for fertility to veterans—and ultimately nonveterans—with spinal cord injuries. Ironically, even when sperm are obtained through these procedures by VA physicians, insemination of the veteran's nonveteran wife cannot be undertaken within the VA.

Although OTA has estimated how much infertility services cost in the general population, estimating similar costs to the VA if it were to provide these services remains problematic until criteria are established for a number of variables. These include specification of the eligibility of veterans and/or spouses for infertility services and types of procedures to be provided. In addition, other factors such as whether these services would be provided in-house or contracted to other facilities will greatly affect estimates. Until these questions are answered, meaningful cost estimates will remain elusive.

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Chapter 11

Ethical Considerations

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Chapter 11

Ethical Considerations

Ethical issues raised by the use of reproductive technologies can be examined in a variety of ways. One method is to study the arguments for and against the use of such technologies, with special emphasis on impacts that are unintended, indirect, and delayed. Another way is to list novel questions raised by the use of reproductive technologies. New ethical questions arise, for example, when third parties are involved in procreative interactions, when sperm and ova are banked for indefinite periods of time, and when surplus human embryos are created. A third method is to list the human values that are generally at stake in the diagnosis and treatment of infertility.

This chapter analyzes ethical arguments, raises novel ethical questions, and surveys relevant human values through discussion of six basic themes that pertain to specific reproductive technologies:

- the right to procreate or reproduce,
- the moral status of the embryo,
- parenthood and parent-child bonding,
- research initiatives and the rights of patients and research subjects,
- truth-telling and confidentiality, and
- intergenerational responsibilities.

CONTEXT OF THE ETHICAL DEBATE

Professional, public, religious, and personal opinions infuse ethical debates about the use of reproductive technologies. The concerns expressed by health care personnel are important, since these individuals are among those most intimately involved in the development and application of such techniques. Position statements have been prepared by relevant committees of the American Medical Association, the American College of Obstetricians and Gynecologists, and the American Fertility Society (1,2,4).

All these professional groups consider at least some, if not all, of the existing reproductive technologies to be morally licit, and all advocate their use in carefully circumscribed situations. Yet all share certain concerns and maintain that the use of these techniques requires careful monitoring. Seen to be especially central are the issues of confidentiality; informed consent; minimization of risk to the pregnant woman, the fetus, or the future child; adequate screening of donors; appropriate handling of embryos; and ongoing evaluation of data obtained through the use of these techniques.

Public opinion is reflected in the many responses of public commissions and groups in this country and throughout the world, particularly since the 1970s (see also apps. D and E). Several themes emerge from such reports:

- support for artificial insemination by husband, artificial insemination by donor, and in vitro fertilization (IVF) as treatments for infertility;
- support for ova and sperm donation (with the exception of the U.S. Ethics Advisory Board, which barred the use of Federal funding, and the French National Ethics Committee);
- support for embryo donation (with the exception of the U.S. Ethics Advisory Board, the French National Ethics Committee, and the Working Party in South Australia);
- the imposition of guidelines and procedural regulations on the use of these techniques, such as restrictions on their use to stable couples and to physicians practicing in appropriate facilities, restrictions for donors of gametes, guidelines on the disclosure of information to protect confidentiality, and provisions to ensure informed consent and to clarify the legal status of children born as a result; and
- great controversy surrounding issues of surrogate motherhood (regardless of whether a fee is paid), the treatment of embryos not

transferred, and the use of these techniques by single women.

Many religious and secular communities emphasize the moral significance of parenthood in a general way, with several variations on this theme. One variation emphasizes the ways in which parenthood enriches the life of individual couples; a second focuses on the importance of parenthood for the social order. These two approaches are best viewed as instances of the appeal to consequences or outcomes of actions. A third emphasizes a theological dimension to parenthood, which is viewed as fulfilling a divine commitment to procreate or as a way of human participation in the divine activity of creating and sustaining life.

Religious traditions offer widespread support for traditional infertility workups and medical and surgical interventions (see app. F). The Protestant, Jewish, and Muslim traditions affirm artificial insemination by husband. The Roman Catholic tradition has special reasons for officially opposing artificial insemination by husband, although some theologians dissent (8,23). Most religious traditions find donation of sperm, eggs, or embryos to be problematic. The Roman Catholic, Orthodox Jewish, Muslim, and some Protestant traditions oppose it, while other Protestant and Conservative and Reform Jewish traditions allow it. Surrogate motherhood in any form is generally opposed by religious traditions. A few religious thinkers, notably biblical theologians (influenced by Old Testament patriarchal accounts about the importance of preserving male lineage) give guarded approval, but these are exceptions. It is important to note that not all members of a particular religious background adhere to the official tradition of their church.

Arguments about the use of reproductive technologies are generally expressed in terms of rights and responsibilities. There are two types of moral rights—liberty rights (negative or noninterference rights) and welfare rights (positive or correlative rights). Responsibilities are also described and sometimes referred to as duties and obligations. These terms are chosen because contemporary ethical discussion, whether it is based on intuition, ethical principles, or faith, is often couched in terms of rights and responsibilities.

A liberty right is defined as a natural right based on human freedom such that any human adult capable of choice has the right to forbearance on the part of all others from the use of coercion or restraint except to hinder coercion or restraint itself, and is at liberty to take any action that is not coercing or restraining or designed to injure other persons (16). In addition, liberty rights indicate the limits of the plausible authority of others, including government. Many people would extend to adolescents, children, and the unborn liberty rights in the form of a right to life (25). A liberty right is a kind of free assertion that requires only noninterference on the part of others, which is why it is characterized as a negative right. Exercising such a right does not require any positive response from others—only that they do not interfere. A liberty right does not claim aid from others in pursuit of a person's own goal. This is unrelated to the issue of whether the aid of others can be paid for or not. The exercise of a liberty right simply does not require such assistance.

A welfare right is a claim asserted by an individual that requires a corresponding response, obligation, or duty on the part of others. Welfare rights depend on a social consensus about the value of the goal. The right to be educated is a welfare right because it involves the assistance, contributions, and resources of others. The United States, for example, has a system of public as well as private education. The right to be educated, particularly at the public expense, is a kind of welfare right because it of necessity involves the talents, energies, and resources of others. It is important to note that the assertion of a *welfare right* does not necessarily indicate the presence or need for what is commonly called a *welfare system*. The claims made by infertile individuals or couples may or may not be something for which they can pay.

The infertile couple or individual must make decisions and come to terms with the problem of infertility in the midst of this professional, public, and religious debate about the ethics of reproductive technologies. The personal experience of infertility diagnosis and treatment may either reinforce or come into conflict with deeply held values. In addition, there are special problems in establishing a definitive resolution of many of these issues because of the plurality of moral viewpoints. In such circumstances, it becomes more difficult to restrict the informed and free collaboration of various parties in achieving conception.

THE RIGHT TO REPRODUCE

A fundamental aspect of much modern moral thinking is the significance of free and autonomous choices. The exact definitions of freedom and autonomy are controversial, but basically considerable moral significance is attached to a person's freedom to make voluntary, uncoerced choices based on self-legislated principles and values. When applied to an evaluation of techniques for preventing and treating infertility, the result is an emphasis on the moral significance of couples and individuals freely choosing to act in accordance with their own values.

A second aspect of modern moral thought is the recognition of duties, obligations, or responsibilities that may limit or constrain human actions. The performance of some types of actions is morally illicit, however valuable the consequences and however much the people involved want to perform them. The exact nature of these constraints and the conditions under which they may be overridden are matters of great controversy, but the basic idea that they exist and do impose limitations on choices is relatively straightforward. In terms of preventing and treating infertility, the emphasis is on examining whether particular techniques do or do not violate any of these constraints.

The right to reproduce appears to be linked to freedom and autonomy in the most basic way: the desire to have children and create a family is a natural expression of generative urges and commitments to religious, ethnic, and familial values that have characterized the human race from its beginning. At present, the right to reproduce is a natural as well as a necessary aspect of human existence for at least some human beings if the species is to continue. The right to reproduce is most often a liberty right in that it demands only that others not interfere. When infertility is not a factor, individuals can exercise their right to reproduce in a way that minimizes claims on the goods, services, and resources of others.

Even as a liberty right, some argue that it is and should be constrained by inordinate population growth. The right does not exist in a vacuum but is tempered by societal circumstances in which people live. China, for example, has a policy limiting to one the number of children married couples in most of the country may have. This public policy is inconsistent with American values and probably would never be adopted in this country, although some have urged that considerations of world population growth should influence the size of American families (21).

The right to reproduce, then, as a liberty right is not particularly controversial, especially when it is asserted by a fertile couple or an individual. When a man or a woman is infertile, however, this right involves claims on others for responses, actions, and services. Such claims, even when those exercising the right have a full ability to pay, must be balanced against a host of other health care needs and priorities. Obviously the right to reproduce can more easily be exercised by those who can pay for needed medical service or intervention. Whether such services *ought* to be for sale is an important question, as is the question of when, if ever, others in society should subsidize or defray the costs of infertility diagnosis and treatment for those who cannot afford needed services. The use of tax dollars for infertility treatment services is also problematic to those members of society who think that some or all reproductive technologies are immoral.

Because it is desirable that procreation be achieved without the direct contributions of third parties or the services of health care providers, it would be better if the condition of infertility did not exist. The reality of infertility makes this a moot point, and it is the basis of a strong ethical argument for a heavy emphasis on preventive measures. For example, based on the ethical principle of respect for persons, it is important that factors that could contribute to infertility, such as a high incidence of sexually transmitted disease resulting in tubal disorders (see ch. 4), be minimized. When attempts to prevent infertility are not initiated early or have failed, some assistance is required for individuals or couples to satisfy their desire to procreate.

When artificial insemination, gamete intrafallopian transfer, sperm and ovum banking, IVF, or surrogacy are needed, exercising the right to procreate makes extensive and in some cases troublesome claims on the interests and resources of others.

In the cases of drug therapy for ovulatory failure and surgical intervention for mechanical failure, the right to procreate can be exercised by infertile couples as long as they are able to procure the necessary expertise and pay for it either directly or through a third party. These technologies are widely available and the provision of them would not compromise the interests of any third party. In fact, infertile couples, health care professionals, and pharmaceutical companies all appear to benefit when such services are appropriately sought.

With artificial insemination, the ethical considerations become more complex. In the case of insemination with the husband's sperm, there is often no compelling objection as long as both partners are fully informed and choose to engage freely in this practice. In rare cases in which the husband is deceased, any harms to the child that might be born associated with not having a living biological father must be weighed against the mother's right to procreate using the stored sperm of a deceased spouse. This right has indeed been claimed by a widow for the use of sperm from her deceased husband (11).

The right to procreate when it involves insemination with a donor's sperm is least problematic when it is asserted by the couple because the husband's desire to see his wife become pregnant has obviously transcended his thwarted desire to be the genetic father. The desires of single women to be artificially inseminated by a donor do not cause any apparent harm to the donor but are most often evaluated with some consideration of the abilities to competently raise a child as a single parent and to the societal consequences of individuals conceiving with the explicit intention of raising a child alone, notwithstanding a trend toward single-parent adoption in this country.

Surrogates and donors of sperm and ova are not necessarily exercising a right to procreate but are contributing their human biological materials for a variety of motives, ranging from pure altruism to a desire to make money. Ethical considerations concerning these transactions center on issues of confidentiality, truth-telling, and the moral status of contracts.

Do infertile couples have a right to financial assistance if they are unable to pay for the cost of diagnosing and treating infertility? The American Fertility Society has noted that if techniques of assisted reproduction are included in the notion of an adequate level of health care, then it is consistent with the work of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research that all citizens be provided with infertility services (2,28). A variation of this position is the view that individuals have a positive right only to a fair share of what may fulfill true human needs (15). It can also be said that infertile individuals and couples are entitled to diagnosis and treatment for infertility if they have had the foresight to select and supplement insurance coverage in a way that such services are included (9).

Providing Federal funds either through a possible extension of Medicaid benefits or by means of a separate enactment is one of the most controversial aspects of complete support of the right to procreate for all infertile couples. Some Americans view selected reproductive technologies as immoral. Spending Federal dollars always raises questions about the allocation of scarce resources. The principal arguments in such debates are:

- *utilitarianism*, that resources should be allocated in a way that promotes the greatest good for the greatest number (24);
- *libertarianism*, that individuals are entitled to whatever resources they possess provided they acquired such resources fairly, that resources may be exchanged commercially or as gifts, and that inequalities in the distribution of resources may be unfortunate but they are not inherently unfair (27);

- *maximin*, that as a matter of first principle, individuals are entitled to equal shares of resources and, as a matter of second principle, inequalities (either excess or scarce resources) should be distributed to benefit the least advantaged provided there is fair equality of opportunity (29); and
- *egalitarianism*, that resources should always be distributed equally (26).

The utilitarian argument can be used to support funding for infertility services by demonstrating how such support would contribute to the greater good. The libertarian argument is largely consistent with the status quo, in which infertility services are available on a limited basis to those who can pay for them. The maximin position could be used to justify some special consideration for infertility services if it could be demonstrated that such services are generally available and that the infertile have the special status of a *least advantaged* group. Finally, an egalitarian argument about the availability of infertility services would support only those services it is feasible to provide to everyone in need. Thus, the arguments about just distribution and the allocation of scarce resources suggest a variety of ethical responses on access to and provision of infertility services for those who cannot currently afford them.

MORAL STATUS OF THE EMBRYO

Human fertilization creates a biological entity that is commonly regarded as more than and different from the precursor germ cells of human sperm and ovum (see figure 11-1). This new entity may develop into a fetus and, eventually, an infant. A number of human embryos are naturally lost when the embryo does not implant in the lining of the womb (see ch. 2).

There is no societal consensus about the earliest point, if any, at which a human embryo should be considered to be a person. At least two important moral or ethical questions are raised about embryos. First, how should we regard or value embryos? Second, what actions are morally acceptable and morally unacceptable with respect to embryos?

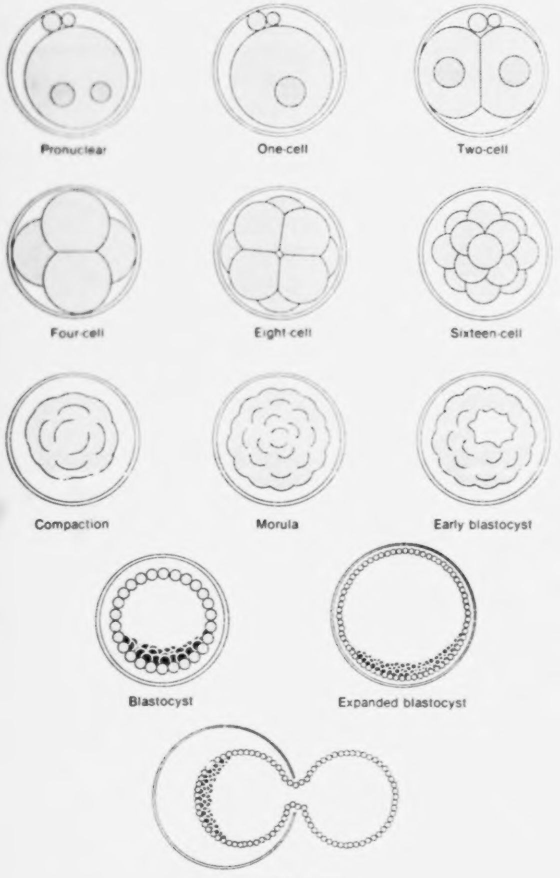
These questions are directly relevant to two of the reproductive technologies examined in this report—IVF and embryo banking. In addition, the freezing of embryos, research using embryos, and in vitro embryo culture are influenced by the way in which the embryo is regarded. In the process of IVF (see ch. 7), it is standard practice to mix several ova with sperm in order to increase the likelihood that several fertilizations will take place. The desired result is the development of embryos. Although the precise moment of fertilization and activation of the new genome may be as late as the four- to eight-cell stage of cell division, ethical questions do arise when more embryos develop than are needed for transfer to the womb or when embryos are created for purposes other than transfer, such as research (19).

It has been suggested that decisions about the use of human embryos can be made depending on the neurological development of the embryo at a given point in time (14,33). The Waller Committee in Victoria, Australia, the Warnock Committee in Great Britain (see app. E), and the 1979 report of the Ethics Advisory Board in the United States all approve of research involving human embryos fertilized in vitro, with varying restrictions but with agreement on a time limit of 14 days after fertilization (35).

There are at least three major philosophical positions on the moral status or meaning of the human embryo. The first is that the embryo is no different from other human biological material and that it has meaning only in terms of the goals and aspirations of others regarding its use and possible maturation. Adherents of this position point out that a large portion of all human embryos are naturally cast off when implantation fails to occur and, further, that an intrauterine device results in the loss of embryos that are even more developed than those that might be discarded in the course of IVF (10,20).

A second position proposes that the embryo, while not a person and while not necessarily requiring the respect and rights due to fully functioning persons in society, is not an objective prod-

Figure 11-1.—Fertilization and Early Stages of Human Embryonic Development



SOURCE: Office of Technology Assessment, 1988

uct or thing, and that it serves as a powerful symbol of respect for life (30,31,34). The embryo, in this scheme, is a "transient identity" and should be accorded "transient rights." These rights are not derived from the values others place on its existence, but from the nature of the potentiality of existence the embryo possesses. Still, while couples have the primary obligation to respect the life of the conceptus, however early its human form, respect for that life may itself lead some to consider abortion on genetic or other grounds. These grounds are open to some public scrutiny and control. When the embryo is at risk—during transfers, freezings, transplants, and future genetic manipulations—public scrutiny may also include public controls. It may be inappropriate to sell such material for research purposes, because that would violate the inherent transient rights of such entities (34).

A third position, which is held by the Roman Catholic church and others, is that the human being must be respected—as a person—from the very first instant of existence (8). From the time an ovum is fertilized, a new life is begun that is of neither the father nor the mother; it is rather the life of a new human being with an individual growth. It would never be made human if it were not human already. "Right from fertilization is begun the adventure of a human life" (32). This position has important implications for any use or treatment of the human embryo that would be different from or less than that afforded to a human person.

In practice, the issue of the use of surplus embryos in IVF is sometimes avoided by implanting all the eggs that are fertilized, increasing the probability of multiple births. One commentator, however, has argued that the deontological (duty-based) problem of the moral status of the embryo in this case gives way to the teleological (outcome-based) problem of how to care for more than one newborn (18). In addition, the presence of multiple fetuses in utero is correlated with lower birth weight per child and greater risks to the mother and to fetal health.

A recent Australian case demonstrates some of the problems and issues associated with the moral and legal status of unimplanted embryos (see box 11-A). From an ethical standpoint, the Rios case illustrates why it is important to discern the moral status of the embryo. Aside from the intents of the parents, who in this case are no longer living, it is difficult to ascertain what duties and obligations are owed the frozen embryos.

The extent to which a human embryo should be respected was addressed in 1986 by the American Fertility Society in its recommendations that:

- cryopreservation should be continued only as long as the normal reproductive span of the egg donor or as long as the original objective of the storage is in force;

Box 11-A.—Australia's Orphan Embryos

In 1981 Mario and Elsa Rios, of Los Angeles, CA, participated in the IVF program at the Victoria Medical Center in Melbourne, Australia. Then age 50 and infertile, Mr. Rios allowed a local, anonymous donor to artificially inseminate three eggs from Elsa Rios, his 37-year-old wife; one was transferred and the other two were frozen for possible use in the future. Mrs. Rios subsequently miscarried and chose not to undertake further transfers at that time. Before she could return and try to use the other embryos, she and her husband died in a plane crash in Chile. Because no will was executed by the wealthy Rios, the California laws of intestate succession seemed to apply. Thus, Mr. Rios' son by a previous marriage was thought to be entitled to his father's share of the estate and Mrs. Rios' 65-year-old mother to her daughter's share. In December 1987, a California superior court declared Mrs. Rios' mother to be sole heir. The medical center in Melbourne then announced that the embryos would be thawed and implanted when a suitable recipient was found, although the survival chances were rated at 5 percent.

SOURCE: Office of Technology Assessment, 1988, based on G.P. Smith, "Australia's Frozen 'Orphan' Embryos: A Medical, Legal and Ethical Dilemma," *Journal of Family Law* (University of Louisville School of Law) 24:27-41, 1985-86; and on "Embryos Will Be Implanted," *New York Times*, Dec. 5, 1987.

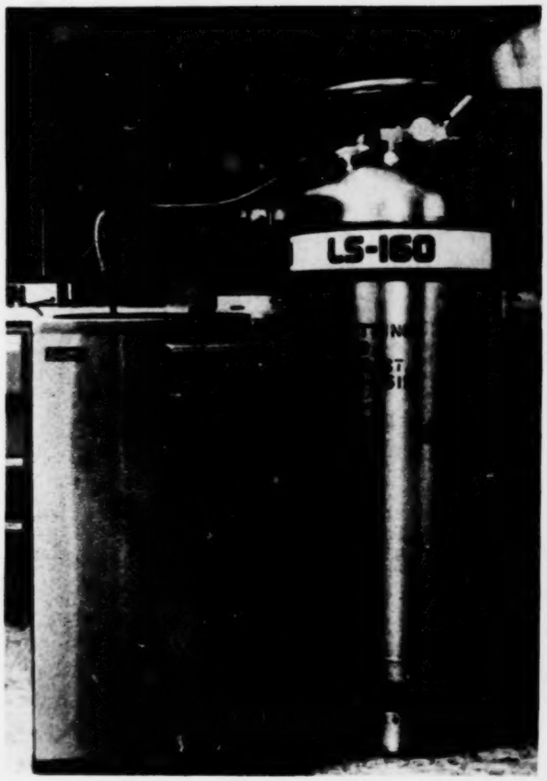


Photo credit: Martin Quigley

Cryopreservation of human embryos in liquid nitrogen storage chamber

- transfer of embryos from one generation to another is unacceptable; and
- formal discussion with the couple should take place in advance to decide whether excess embryos can be transferred to other couples, used for approved research, examined, or discarded (2).

PARENTHOOD AND PARENT-CHILD BONDING

Opinion differs on the extent to which the genetic, gestational, and social functions of parenting can be separated and yet preserve the welfare of parents and children. Some who contend that new reproductive technologies are ethically acceptable regard parenthood as a relationship defined by acts of nurturing as opposed to acts of conceiving and giving birth. Others, although recognizing that acts of nurturing and generating life are distinct and that acts of nurturing are included in the meaning of parenthood, affirm that acts of generating life are parental in nature (22).

Bonding between a human infant and an adult is a prerequisite to the physical and psychological growth of the child and creates and sustains the abilities of the parents to nurture the child. Do parents and children possess a possible welfare right to at least the minimum conditions necessary for human bonding to take place? Now that it is possible for a child to have a total of five "parents"—three types of mothers (genetic, gestational, and rearing) and two types of fathers (genetic and rearing)—which of these parents has the right to form a parent-child bond? Now that it is possible through surrogacy arrangements and artificial insemination by donor for individuals to plan to create a single-parent family, does this violate a possible right of the child to bond to more than one parent? These questions have important implications for the way in which parent-child bonding takes place and for possible new variations in the developing identities of some children.

Any one of these variations on the theme of the moral significance of parenthood and the importance of parent-child bonding has considerable relevance to an ethical assessment of techniques for preventing and treating infertility. Depending on a number of factors (e.g., the way in which a particular variation views parenthood and the particular treatment used), the importance of the parent-child bond may lead to a positive ethical evaluation of techniques for preventing and treating infertility (6).

RESEARCH INITIATIVES AND THE RIGHTS OF PATIENTS AND RESEARCH SUBJECTS

In the process of diagnosis and treatment for infertility, individuals or couples may find themselves in the role of research subjects as well as patients. Typically they start out as patients and are presumably informed about and give consent to each step of the diagnostic process. Couples are asserting a right to be treated for their infertility using medical therapy.

To expand and improve on the scientific basis of diagnosis and treatment for infertility, information about patients and their problems must be gathered and recorded in a systematic way. This is an aspect of medical treatment that can result in descriptive research about the course and outcome of medical therapy. As long as patients are informed that facts about them are being collected, in part for research purposes, and that their anonymity will be preserved, the benefits of this accumulating database seem to outweigh any possible harms or inconveniences to the infertile couples. These couples are now, in addition to being patients, also serving as research subjects although they may always choose to exercise their right to not participate. This pattern is not substantially different from that conducted in other areas of human health and disease.

A more troubling research aspect of infertility diagnosis and treatment (as well as the diagnosis and treatment of many other conditions) is how to make appropriate use of new technologies that have not yet entered the realm of tried and true medical therapy. Which reproductive technologies, if any, are more experimental than therapeutic? Do infertile couples become research subjects as a result of the experimental nature of the technologies that may be used in their treatment? Is there a subtle pressure occasionally present that the development of new knowledge can sometimes justify placing a human subject at a disproportionate risk or engaging in research with inadequate informed consent procedures?

All the parties interested in effective infertility diagnosis and treatment share a concern about how to distinguish properly among medical therapies, clinical trials, and clinical experiments. A specific reproductive technology may be *used* in a standard way in one instance and in a novel or experimental way another time. So it is not only the technologies themselves, but the way in which they are used, that determines whether a patient receives care that is more experimental than therapeutic (7).

Clinicians and researchers note that the problem of consistently developing medical therapies is particularly acute in the treatment of infertility because a de facto moratorium since 1980 on Federal funding for many forms of research involving fertilization of human egg and sperm has impeded the development of knowledge about fertility, infertility, and contraception (see ch. 15).

Although research initiatives may result in the steady transition of reproductive technologies from the domain of experimental to that of standard medical therapy, the rights of patients who are being treated for infertility to be appropriately informed about the research aspects of their treatment persist. In the course of diagnosing and treating infertility, the liberty or noninterference rights of scientists to pursue research and of physicians to practice medicine are constrained by the correlative right of infertile couples to be informed about the experimental nature of selected reproductive technologies.

Individuals and couples with problems of infertility are an extremely vulnerable population group. Because of their strong desire to exhaust all possibly successful avenues of treatment, an attitude they share with those who are considering participation in research under the pressure of severe illness, their ability to give free and informed consent is to some extent always compromised. For this reason, it is particularly important that care be taken to carefully inform infertile couples when new reproductive technologies are suggested as possible methods of treatment. The special vulnerability of this group makes quality control of reproductive technologies a vital societal concern (see ch. 9).

TRUTH-TELLING AND CONFIDENTIALITY

Infertility prevention, diagnosis, and treatment are interactive processes in which the infertile individuals, physicians, and others exchange information, make evaluations, and even offer predictions. All parties to these interactions have a right to know the truth. At least two moral arguments for telling the truth can be cited: Truth-telling is a general requirement for an action to be moral, and truth-telling generally has the best consequences in the realms of personal interaction (37). A common counterargument is that the truth might result in some harm, such as increased personal suffering or a denial of access to a desired service. Using the language of moral rights mentioned earlier in the chapter, the right to be told the truth is a claim right involving the full disclosure of otherwise unknown or unavailable information. The liberty right to be left alone, or free from harm, might be best exercised with or without the truth.

Infertile individuals and couples who seek diagnosis and treatment are not asking merely to be left alone. In their quest for a solution to their infertility, truthful information is an important basis for accurate diagnosis. It is important for the physician to know, for example, about any occurrence of sexually transmitted disease in order to make an accurate diagnosis and to devise an appropriate treatment. It is also important for the physician to know the extent of previous diagnostic workups and treatment failures.

By the same token, it is important for the patient to know the truth about a specific treatment and the likelihood of success of a given effort. A common criterion used in evaluating various IVF programs is the pregnancy rate achieved by a specific program. There is considerable variation, however, in the way that this rate is reported. The variations include reporting in terms of pregnancies per ovarian stimulation cycle, and pregnancies per embryo transfer (see ch. 9). A group of prominent clinicians has noted that what constitutes pregnancy is confusing to the lay public. Couples who seek treatment for infertility are really interested in taking home babies, and a claim to a high pregnancy rate based on a limited number of chemical pregnancies, for example, is misleading (5). One commentator makes the point that technically accurate statements that convey misleading messages are no less a violation of the principle of truth-telling because their content happens to be technically true (36).

One area in which physicians have made judgments that truth-telling may not ultimately be of benefit to the patients they are trying to treat is in filing insurance claims on behalf of patients. The great variation in coverage among third-party payers may lead to physician subterfuge about the actual services provided and the goals of treatment (see ch. 8). This is a case in which the physician may knowingly compromise his or her own integrity in order to assist patients in acquiring reimbursement. Physicians who do this have made the judgment that the negative consequences of telling the truth in a way that corresponds to insurance reimbursement categories outweigh the general moral requirement to tell the truth.

A major feature of the physician-patient relationship is the expectation that the highly charged personal information pertaining to the diagnosis and treatment of infertility will be held in confidence. This is true for most of the interactions that take place between physicians and patients but is particularly pressing in an area of medical practice where problems are of such an intimate nature and strike at the heart of personal and family relationships. The fundamental statement concerning medical confidentiality appears in the Hippocratic oath:

> What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things to be shameful to be spoken about (12).

This principle has been reiterated in modern times by many groups and in numerous codes of professional ethics. It has been maintained, for example, that a doctor owes a patient absolute secrecy on all that has been confided or that the doctor knows because of the confidence entrusted in him or her, and that the patient has the right to expect that all communications and records pertaining to care should be treated as confidential (3,4).

The use of reproductive technologies can place a strain on maintaining confidentiality in several important ways. The use of donor ova or sperm involves the transfer of relevant information about the donor although the anonymity of the donor can be maintained. It may be impossible to treat the problem of infertility as a problem of the couple if one partner holds the physician to a principle of confidentiality, for example, with respect to past sexual practices. The maintenance of confidentiality is also linked to the reestablishment of privacy concerning sexual matters that may be essential to the well-being of the couple after the crisis of infertility has been resolved.

INTERGENERATIONAL RESPONSIBILITIES

One important aspect of ethical arguments for and against specific reproductive technologies is the significance of considering the consequences of individual actions and social practices for all those affected. These individuals can include those who perform the actions or participate in the practices, or they may be other members of society. Any evaluation must consider the consequences of these techniques for the infertile couples, for their prospective children, and for the rest of society (6).

Some argue that the use of reproductive technologies carries with it the duty of not harming either the infertile patient or the resulting embryo, fetus, and child. The ethical principle of nonmaleficence has a long tradition in medical ethics that many trace back to the Hippocratic oath (36). In addition, others would argue that there is a strong obligation to circumvent or treat the problem of infertility in ways that do not harm future generations in general. Does one generation have obligations to another and, if so, how are these duties weighed against individual needs and desires?

These questions are particularly relevant to issues of confidentiality and truth-telling in the context of donor gametes (ova or sperm) and surrogate motherhood. Should a child be told that his or her rearing parent is not the child's genetic and/or gestational parent, and also how he or she was conceived? Should information about a child's biological origin be kept on file? Should a child who is not living with his or her father or mother be entitled to at least some information about this genetic parent? Should a child be entitled to know the identity of the genetic father or mother and thus be afforded the opportunity to contact this parent?

In his book *The Philosophy of Right*, G.W.F. Hegel stated:

> Children are potentially free and their life directly embodies nothing save potential freedom. Consequently they are not things and cannot be the property either of their parents or others (17).

Children are ends in themselves and not merely the means or objects of the goals of their parents. If this is true, then it would be unacceptable to utilize a reproductive technology that would impinge on the freedom or autonomy of children. One philosopher argues that duties to future generations must be much weaker than duties to contemporaries, for contemporaries are actual persons who can have actual views about what is important (13). Even so, there is an important argument that it is prudent to support those practices that are least likely to be harmful to the next generation.

Reproductive technologies also raise intergenerational concerns about the use of resources. Increased funding for infertility research can have important benefits for humanity but this claim for the research dollar has to compete with other research interests. In addition, any general shift in the reproductive years of the population as a whole has important economic and demographic implications for the generations that follow.

SUMMARY AND CONCLUSIONS

For individuals and couples with problems of infertility, the right to procreate may be exercised as a simple liberty right involving the noninterference or forbearance of others or as a welfare right that makes significant claims on technology and the expertise and resources of others. The right to reproduce becomes problematic when it involves large financial resources extending beyond those available to an infertile individual or couple. Given the fundamental nature of the desire to procreate, however, it seems desirable that individuals from a variety of backgrounds have some access to reproductive technologies.

The right to reproduce becomes more difficult to justify when it begins to compromise the interests of a third party. There is a strong moral sentiment that the exercise of the right to procreate by some individuals should not result in the exploitation of women, for example, in surrogate mother arrangements. Alternatively, some moral support exists for the view that in a free society it is possible and should be legal to give the gift of genetic or gestational surrogacy to an infertile couple.

A strong ethical argument can be made that resources and support should be devoted to the prevention of infertility in order that the right to procreate can most often be expressed as a liberty right. Individuals have an interest in avoiding any curtailment of their reproductive capacity when they wish to reproduce. This places a heavy emphasis on the eradication of factors that lead to infertility.

The moral status of the human embryo is a subject of considerable debate. Many people have made judgments about whether the embryo has the status and meaning of a person. In addition, cryopreservation of embryos presents legal and ethical questions about the rights of such entities and any duties and obligations owed to them. The unresolved debate about appropriate uses of human embryos and the de facto moratorium on Federal support for IVF research have impeded the growth of new knowledge about fertility, infertility, and contraception.

Reproductive technologies make it technically possible for a child to have a total of five "parents" —three types of mothers (genetic, gestational, and rearing) and two types of fathers (genetic and rearing). These possibilities change the nature of parenting and may have implications for the ways in which parent-child bonding takes place. Such bonding has important psychological benefits for parents and is essential to the developing personalities of children.

The right to conduct research is a noninterference or liberty right as well as a welfare or correlative right. The right to pursue research is always balanced against other societal goods, and the resources to conduct research are always limited. Infertile patients have a right to know when their treatment is in the realm of proven medical therapy or is essentially experimental.

Telling the truth and maintaining confidentiality are important aspects of the physician-patient relationship. The intimate nature of the diagnosis and treatment of infertility and the special features of reproductive technologies that make use of donor ova or sperm complicate simple ethical imperatives to tell the truth and to hold personal information in confidence. A strong argument can be made that individuals have a duty to refrain from utilizing reproductive technologies in ways that could possibly harm future generations or make disproportionate claims on the resources of existing generations.

Most religious traditions in the United States:

- support the treatment of infertility when such treatment involves traditional drug therapy or surgical intervention, and accept the moral licitness of such treatments;
- accept the moral licitness of artificial insemination by husband, have considerable hesitation about artificial insemination by donor, and show even less support for artificial insemination of single women with donor sperm;
- support IVF as long as only spousal gametes (ova and sperm) are used and as long as no embryos are wasted, though support lessens to some degree when there is early embryo wastage and to a much greater degree when donor gametes are used; and
- oppose surrogate motherhood in both its genetic and gestational forms.

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Chapter 12

Constitutional Considerations

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Chapter 12

Constitutional Considerations

The extent to which States can ban or regulate noncoital reproduction depends on the extent to which procreation is protected by the U.S. Constitution. A State constitutional guarantee of a right to privacy or a right to procreate can also affect the extent to which a State could regulate noncoital reproduction, but a discussion of State constitutions and their propensity for protection in this area is beyond the scope of this report.

The more zealously procreation is guarded by constitutional guarantees, the more compelling and narrowly drawn must be State efforts to regulate or restrict use of procreative techniques. Procreative freedom can extend to questions of *who* may procreate and *how* they may procreate (43).

This chapter examines two aspects of reproductive liberty: the freedom *to* procreate (i.e., the extent of the right held by married and single, by heterosexual and homosexual, to conceive, bear, and raise children) and freedom *in* procreation (i.e., freedom to choose noncoital reproductive techniques, and the limits of legitimate State regulation of that choice).

FREEDOM TO PROCREATE

The right to procreate, that is to bear or beget children, is widely considered one of the rights implied by the Constitution. It is grounded in both individual liberty and the integrity of the family unit, and is viewed as a "fundamental" right, one that is essential to the notion of liberty or justice.

The Supreme Court has not explicitly considered whether there is a positive right to procreate —i.e., whether every individual has a right to actually bear or beget a child. It has, however, considered a wide range of related issues, including the right of the State to interfere with procreative ability by forcible sterilization, the right of individuals to prevent conception or continued pregnancy, and the right of individuals to rear children and to form nontraditional family groups.

Photo credit: U.S. Department of Commerce, Bureau of the Census

A "Right To Have Offspring"?—*Skinner* v. *Oklahoma*

The State's ability to interfere with natural reproductive abilities has been considered in two cases: *Buck* v. *Bell* and *Skinner* v. *Oklahoma* (4,47). In the 1927 *Buck* decision, the Court upheld sterilization of the mentally retarded on the basis of eugenic considerations. Since 1927, the eugenic justifications relied on in *Buck* have been repudiated (9), and the 1942 *Skinner* decision has become the more durable statement on forced sterilization. *Skinner* held that the State could not use sterilization to selectively punish certain classes of repeat felons. Although the decision focused largely on the unfairness of applying the punishment to some criminals and not others, thereby violating the 14th Amendment's equal protection clause, the Court did discuss the tremendous importance of reproduction. The discussion was important to the Court's decision to apply a strict level of scrutiny to any State effort to use interference with procreation as a form of punishment or deterrence, and to be particularly scrupulous in reviewing any State effort to arbitrarily destroy procreative ability:

> This case touches a sensitive and important area of human rights. Oklahoma deprives certain individuals of a right which is basic to the perpetuation of a race—*the right to have offspring* (emphasis added).
>
> [This legislation] involves one of the basic civil rights of man. Marriage and procreation are fundamental to the very existence and survival of the race. . . . There is no redemption for the individual whom the law touches. He is forever deprived of a basic liberty (47).

The *Skinner* decision is notable for its explicit mention of a "right to have offspring." Although procreation is not mentioned explicitly in the Constitution, the Court characterizes it as a basic human right, justifying a strict level of scrutiny for any State action that would interfere with its exercise. Further, while the grouping of marriage and procreation in the same breath indicates that the Court considered the two as intimately related, it nevertheless recognized a distinct "right" to procreate and seemed to characterize the right as one held by the individual, not the couple.

Individual Rights and Freedom To Procreate

The implication that procreative rights are held by individuals rather than by married couples is further supported by other Supreme Court decisions concerning reproductive and familial liberties. In 1965, the Court held in *Griswold v. Connecticut* that married couples have a right to be free of State interference in their decision to obtain and use contraceptives, basing its decision on the concept of marital privacy, a sphere of personal interest largely immune from State regulation (17). In the 1972 decision *Eisenstadt v. Baird*, the Court explicitly extended this principle to individuals, when it held that the individual's right to obtain and use contraceptives is also protected by the right to privacy, and that marital privacy is simply one aspect of a more general right to privacy. That case featured one of the Court's strongest statements in support of an individual's liberty to make decisions concerning reproduction:

> It is true that in *Griswold* the right of privacy . . . inhered in the marital relationship. Yet the marital couple is not an independent entity with a mind and heart of its own, but an association of two individuals each with a separate intellectual and emotional makeup. If the right to privacy means anything, it is the right of the *individual*, married or single, to be free of unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child (12).

Similarly, in cases upholding the right to terminate pregnancy, the Court has made clear that the right extends to married and unmarried, adult and minor, even if some narrowly tailored regulation is permitted to protect maternal health or to ensure informed consent by a minor (2,20,33,45).

These decisions appear, then, to support the idea that the right to privacy, including the right to procreate, extends to individuals, married or not. Certainly, for example, no State could require contraceptive use by unmarried persons in order to prevent them from procreating. However, as most of the reproductive liberty cases considered the right to prevent conception or continued pregnancy, they are not precisely on point and thus there is still some room for doubt (48).

Permitting unmarried persons to use contraceptives to prevent their unwilling formation of families is consistent with traditional State preferences for two-parent homes. Acknowledging that unmarried persons have a right to form families is somewhat different.

Further, Supreme Court decisions have upheld State authority to regulate sexual activity, including the recent *Bowers* decision, upholding prohibitions on specific sexual acts; the *Bowers* decision also stated in dictum that State laws against sexual activity outside marriage could continue to be upheld (3). ("Dictum" is commentary that is not strictly necessary to the decision on the case before the court. Judges use it to explain their reasoning and to draw analogies to other fact situations, and it can provide a clue as to future judicial decisions in related areas of law.)

Photo credit: Library of Congress

Nontraditional couples may want to use noncoital reproductive technology.

If the Supreme Court were to approve a prohibition on coitus outside marriage, it would be somewhat inconsistent with a stance that those same unmarried persons have a right to achieve by noncoital means what they may not attempt by coitus—i.e., to procreate. If the *Bowers* dictum is taken at face value, then it would seem unlikely that the Court would find a constitutional right for unmarried persons to use noncoital means to procreate.

Thus, it is still somewhat unclear that the Supreme Court would find that the right to procreate is an aspect of individual rights. There is little doubt, though, that it exists as an aspect of marital privacy and family autonomy. When procreation is viewed not as an individual right, but rather as an aspect of family privacy, limits on governmental intervention will be affected by whether the family group under consideration is constitutionally protected.

Family Privacy and Freedom To Procreate

Family privacy is an outgrowth of a history of leaving many decisions concerning marriage, childbirth, and childrearing relatively free of governmental intervention (7). For some married, infertile couples, expanding their families will entail the choice to use noncoital reproductive techniques. Nontraditional parents, such as single parents or unmarried heterosexual or homosexual couples, may need or want to use these techniques as well. State authority to regulate who may engage in noncoital reproduction may depend in part on whether the choice to procreate this way is an aspect of family privacy, and, if so, whether that privacy extends to all family forms or only to married couples.

State authority to regulate family structure and sexual preferences has had a mixed history in the United States (18). An 1878 decision affirmed that the State has authority to outlaw polygamy (40), and the U.S. courts have never recognized a right to marry someone of the same sex, despite recognition of a general right to marry (27,29,59). The Supreme Court has countenanced societal condemnations of "irresponsible liaisons beyond the bounds of marriage" (58), "illegitimate relationships" (54), and homosexuality (3), and as a result courts have frequently lacked sympathy for the equal protection claims of unmarried parents.

On the other hand, nontraditional parents are slowly becoming more successful in their efforts to adopt children or to have custody and visitation rights after divorce (24,50). Further, a number of decisions have emphasized that the family unit need not be defined by specific generations living together (30), by genetic relationships (49), or by marriage (51). In one case, the Court commented that "the Constitution prevents [government] from standardizing its children—and its adults—by forcing all to live in certain narrowly defined family patterns" (30).

More recently, the Supreme Court has stated that the degree to which a relationship deserves freedom from governmental interference depends on "where that relationship's objective characteristics locate it on a spectrum from the most intimate to the most attenuated of personal attachments" (41). This freedom of association logically extends to nontraditional as well as traditional families. In its *Roberts* decision, the Court stated:

> [B]ecause the Bill of Rights is designed to secure individual liberty, it must afford the formation and preservation of certain kinds of personal relation-

> ships a substantial measure of sanctuary from unjustified interference by the State. . . .
>
> [P]ersonal bonds have played a critical role in the culture and traditions of the Nation by cultivating and transmitting shared ideals and beliefs; they thereby foster diversity and act as critical buffers between the individual and the power of the State. Moreover, the constitutional shelter afforded such relationships reflects the realization that individuals draw much of their emotional enrichment from close ties with others. Protecting these relationships from unwarranted State interference therefore safeguards the ability independently to define one's identity that is central to any concept of ordered liberty. The personal affiliations that exemplify these considerations, and that therefore suggest some relevant limitations on *the relationships that might be entitled to this sort of constitutional protection, are those that attend the creation and sustenance of a family*—marriage; childbirth; the raising and education of children; and cohabitation with one's relatives (citations omitted; emphasis added) (41).

Nontraditional families—whether they consist of a single parent and child, same-sex parents and child, or multiple parents due to divorce and joint custody of child—provide emotional satisfaction and expression of personal identity in the same fashion as more traditional marital unions. Logically, then, this reasoning would extend the freedom of association and the freedom to procreate to any family form. However, the difficulty of reconciling this reasoning with that which continues to support State authority to prohibit certain forms of sexual activity among consenting adults makes it impossible to predict with certainty the Supreme Court's likely reaction to an assertion that nontraditional family privacy supports a right to procreate that extends to the use of noncoital reproductive techniques.

RESTRICTIONS ON FREEDOM IN PROCREATION

Given that there is a right to procreate for married couples, and possibly for all individuals, one commentator argues that married couples have a right to use any means to procreate, including noncoital techniques:

> The couple's interest in reproducing is the same, no matter how conception occurs, for the values and interests underlying coital reproduction are equally present. . . . The use of noncoital techniques such as IVF [in vitro fertilization] or artificial insemination to unite egg and husband's sperm, made necessary by the couple's infertility, should then also be protected (44).

Noncoital reproduction need not be used solely to overcome infertility, however, as donor gametes might be used to avoid passing on a genetic disorder or to enhance the possibility of obtaining desirable characteristics, and surrogate mothers could be hired for convenience or to overcome the lack of a female partner. The commentator argues that freedom in procreation extends to use of noncoital reproductive techniques for any or all of these purposes:

> The right of married persons to use noncoital and collaborative means of conception to overcome infertility must extend to any purpose. . . . Restricting the right . . . to one purpose, such as relief of infertility, contradicts the meaning of a right of autonomy. . . .
>
> Procreative autonomy is rooted in the notion that individuals have a right to choose and live out the kind of life that they find meaningful and fulfilling. . . . [M]any people . . . consider reproduction meaningful only if the child is in good health. . . .
>
> The freedom to select offspring characteristics includes the right to abort fetuses or refuse to implant embryos with undesired gender or genetic traits. Just as people are now free to pick mates, they would have the freedom to pick egg, sperm, or gestational donors to maximize health or desirable physical features. . . . [T]his freedom would [also] provide the right genetically to manipulate egg, sperm, or embryo to provide a child with a certain genetic makeup (43).

This expansive view of procreative autonomy goes considerably beyond the mere "right to have offspring," as expressed by the Supreme Court in *Skinner*, and encompasses the right to plan completely, within technological limits, the means and results of conception.

Given the present legality of State regulation of sexual relations among consenting adults and the doubt concerning whether the right of an unmarried individual to procreate even by coital means is protected by the Constitution, it may be premature to discuss these extensions of the basic right to have offspring. That right, as expressed by noncoital reproduction, already opens up the possibility of competing concerns that are the subject of legitimate State regulation. The 1988 New Jersey Supreme Court decision concerning surrogacy stated:

> The right of procreation is best understood and protected if confined to its essentials, and when dealing with rights concerning the resulting child, different interests come into play (21).

The fact that a right exists and is classified as of "fundamental" importance does not act as an absolute bar to State regulation.

Both explicit and implicit individual rights can be limited by the State, if the rationale is compelling and the methods used are the least restrictive possible. Thus, the right to free speech may be sacrificed where its exercise causes a clear and present danger. The classic example is the prohibition on shouting "fire" in a crowded theater. The freedom of peaceable assembly may be regulated by local laws requiring permits to use certain public areas, if the permits are necessary to ensure public safety and convenience and if they are granted in a nondiscriminatory fashion. The exercise of the right to privacy, such as choosing to terminate a pregnancy, may be left unassisted, as when governmental programs fail to pay for the necessary services even when individuals cannot afford them otherwise.

These three areas of State influence—prohibiting, regulating, or failing to assist the exercise of a right—are permissible under more or less compelling circumstances. However, there is much room for disagreement concerning what constitutes a compelling circumstance, or whether the means chosen by the Government are the least restrictive possible.

As a constitutionally protected aspect of personal privacy, preventing continued pregnancy can be subject only to minimal Government regulation (6,15,33,52) carefully tailored to accomplish the one legitimate Government purpose—protecting health—with only minimal interference with the individual's rights. It would seem consistent that the Government could not prohibit the use of medical or surgical treatments to cure or circumvent infertility, although it could ensure the quality of the medical care by appropriate regulation (see ch. 9). Therefore, regulation to ensure that infertile individuals are given adequate information to make an informed choice among available infertility treatments, to provide offspring with nonidentifying medical and possibly personal information on their genetic and gestational parents, and to protect gamete recipients from transmissible infectious disease would seem both within State power and not unduly burdensome on the exercise of the right to procreate.

At the same time, the Government does not appear to have the obligation to finance the choice to use noncoital reproduction. At least with respect to abortion, legislation prohibiting Government funding has been upheld (19,28) on the basis that failure to fund abortions does not impinge on a woman's right to have an abortion. By failing to fund abortions for poor women, the Court reasoned, the State places no obstacles in the pregnant woman's path to an abortion—i.e., the State did not create the woman's poverty that prevents her from obtaining an abortion. This makes the regulation constitutional as long as it rationally furthers any legitimate State purpose.

Similarly, governmental policies to give financial support to infertile couples using treatments that do not require donor gametes, surrogates, or maintenance of extracorporeal embryos while not financing other techniques would probably be justifiable on the basis of State policy to encourage the use of reproductive techniques that minimize difficult family law questions or questions concerning the appropriate management of embryos (see chs. 9, 13, and 14).

When treatment of infertility involves third parties other than medical personnel, however, the question also arises whether protection of their interests or societal interests could justify interfering with procreative liberty. "A person's rights of privacy and self determination are qualified by the effect on innocent third persons," said the New Jersey Supreme Court decision on surrogacy arrangements (21). Such third parties include gamete donors and surrogates, and societal interests might be expressed with respect to management of extracorporeal embryos or the generalized effect of commercialization of noncoital reproduction.

Protecting the Extracorporeal Embryo

Some techniques for noncoital reproduction, such as in vitro fertilization or embryo donation, involve the creation or maintenance of an extracorporeal embryo. The legal status of such an embryo, and the protection the State can afford it against destruction or manipulation, are unclear. Guidance can be found in the series of decisions, beginning with *Roe v. Wade*, that permit a woman to choose to discontinue a pregnancy. Thus, where an individual woman's right to terminate pregnancy is balanced with a possible State interest in allowing all potential children to be brought to term, the interests of the woman are superior.

If the decision to become pregnant is similarly an aspect of the right to privacy and to procreate, then one would expect that the State could not easily prohibit all use of techniques that necessitate the creation of extracorporeal embryos, at least for those couples who cannot conceive by any other means. This is particularly true in light of the fact that the embryo does not have the status of a "person" under the 14th Amendment (45) and therefore any interests ascribed to it are unlikely to outweigh the identifiable interests of living adults seeking to exercise their right to procreate.

The fact that creation of extracorporeal embryos is protected for the purpose of infertility therapy does not necessarily mean, however, that management of these embryos may not be subject to State regulation. Efforts could be made to regulate certain forms of embryo research, or the discard, transfer, or cryopreservation of embryos (see chs. 9 and 13).

In the interest of emphasizing the value placed on embryos, States could try to ban the discard and destruction of embryos not transferred following IVF. Such a ban would not directly violate the principles laid down in *Roe v. Wade*, as absent a rule that an embryo must be reimplanted in the egg donor's uterus, the prohibition does not interfere with her right to make decisions concerning the continuation of pregnancy. It does, however, arguably violate the parental or property rights of the gamete donors to dispose of their embryo as they see fit. Further, if the prohibition on discard were accompanied by a requirement that the embryos be frozen and offered for transfer to someone who wished to "adopt" them, then it might violate the gamete donors' desire to avoid having unknown genetic offspring.

This latter argument is weakened, however, by the fact that there are already situations in which individuals are not allowed to prevent the birth of unwanted lineal descendants. A man may not force a woman to have an abortion, even if he does not desire to have a child, and his desire to avoid fatherhood will not eliminate his obligation to support that child if born. Further, a physician performing a postviability abortion has an obligation to try and save the fetus regardless of the mother's desires (8), unless to do so would threaten the mother's physical or psychological health (10, 45,55). Although these cases are distinguishable, it does appear that States might be able to place some limitations on the destruction of embryos not transferred following IVF (44).

The constitutionality of State efforts to limit the use of cryopreservation of embryos is similarly difficult to assess. Cryopreservation currently results in a loss of a substantial number of embryos (see ch. 15). State interests in preventing the loss of embryos could be used to try to justify limitations on the use of the technique. Other rationales that might be suggested include an interest in preventing the development of embryo banks, and the desire to avoid complex family relations created when children are born long after the deaths of their genetic parents. Further, the procedure is not strictly necessary to achieve procreation, as fresh embryos could be used instead, and so it may be argued that prohibiting cryopreservation of embryos does not interfere directly with the right to procreate.

Balanced against these considerations is the fact that the procedure is used so that further laparoscopies and their attendant risks can be avoided. This medical justification may be sufficient to justify the increased risk to the embryo's potential for future development. Further, State rationales based upon concern for avoiding the destruction of embryos must be considered in light of the very high rate of embryonic loss in natural reproduction (see ch. 2), and the fact that cryopreservation is usually undertaken to facilitate future implantations and births. Thus, the State interest may arguably be viewed as overly solicitous on the one hand, and self-defeating on the other.

Prohibitions on embryo research, and particularly on the deliberate creation of embryos for their use in research, might possibly be constitutional, as there is no direct interference in an individual interest in procreation or bodily autonomy. Although prohibitions on research with embryos might slow or even halt the development of certain types of infertility treatments, as well as other medical developments, the State interest in protecting embryos might be sufficient to justify this indirect interference with the future expression of the right to procreate. Medical researchers could argue that such a prohibition also interferes with their First Amendment right to freedom of expression, as it interferes with the development and dissemination of information concerning embryonic development. This would be, however, a novel interpretation of the First Amendment (42), and it is unclear how courts would react.

Regulating Surrogacy Arrangements

Prohibiting all forms of surrogacy, including those involving no compensation beyond direct expenses, raises the question of interference with the right to procreate for couples, as opposed to individuals. Most commonly, surrogacy involves a man who hires a woman to be artificially inseminated with his sperm and to relinquish the resulting child to him and his wife. The man in this situation is fertile, and can procreate coitally without surrogacy, albeit outside marriage. His wife will not procreate even if surrogacy is used, but instead will adopt a child. Thus, limitations on surrogacy would not interfere with the man's ability to procreate, nor would it affect his wife's inability to procreate. Rather, it interferes with their ability, as a couple, to raise a child genetically related to at least one of them.

The Michigan appellate court in *Doe v. Kelley* characterized surrogacy as an effort to use contract law to further the statutory right to use adoption to change the legal status of a child, rather than an effort to exercise the right to procreate per se (11).

The New Jersey Supreme Court endorsed this line of analysis in its 1988 *Baby M* decision, concerning a custody dispute between Mary Beth Whitehead, a surrogate mother, and William Stern, who had hired her (see box 14-A in ch. 14 for further details on this case):

> The right to procreate very simply is the right to have natural children, whether through sexual intercourse or artificial insemination. It is no more than that. Mr. Stern has not been deprived of that right. Through artificial insemination of Mrs. Whitehead, Baby M is his child. The custody, care, companionship, and nurturing that follow birth are not parts of the right to procreation; they are rights that may also be constitutionally protected, but that involve many considerations other than the right of procreation (21).

This analysis does not fully address exercising the right to procreate by hiring surrogate gestational mothers, who bring to term a child to whom they are not genetically related. In such cases, this form of surrogacy may be the only means by which the genetic mother can expect to pass her genes on to the next generation. Further, prohibiting women to earn money by selling their ova, when men are permitted to sell sperm, may violate the Equal Protection Clause of the 14th Amendment, even if ova sales could be more closely regulated in light of the greater medical risks they pose to donors.

The point made by the *Doe v. Kelley* and *Baby M* courts can be recast as the question of whether there is a right to obtain custody of a biologically related child. To the extent that surrogacy ensures a man (and through gestational surrogacy, possibly his wife) the ability to raise a genetically related child, rather than the ability to procreate, it is really a technique for obtaining custody. In the past, no constitutional right to custody has been identified when there is a dispute between biological parents (although courts have been constitutionally permitted to give custodial preference to a biological parent over a nonbiological parent).

> There is nothing in our culture or society that even begins to suggest a fundamental right on the part of the father to the custody of the child as part of his right to procreate when opposed by the claim of the mother to the same child (21).

Thus, prohibitions on surrogacy raise a somewhat more attenuated consideration of interference with the right to procreate.

The question of the constitutional right to use a surrogate mother has been discussed by a few State courts. Although reversed on appeal, the *Baby M* trial court decision considered surrogacy a constitutionally protected option for a couple seeking a child:

> If it is the reproduction that is protected, then the means of reproduction are also to be protected. . . . This court holds that the protected means extends to the use of surrogates. . . . *The third party is essential if the couple is to rear a genetically related child* (emphasis added) (21).

For a married, infertile couple, other State courts might accept the same reasoning, especially if they view the right to procreate as encompassing not only the right to gestate or to pass on genetic heritage, but also as a right to enjoy the fruit of that procreation and to rear the resulting child.

Should the intended rearing parents be nontraditional or seek a surrogate for reasons other than infertility or fear of passing on a serious genetic disorder, courts may be less sympathetic to the claim of constitutional protection, particularly if the court views freedom to procreate as an aspect of marital privacy rather than of individual privacy, as discussed earlier in this chapter. For example, where surrogacy is sought by a single man as a method for forming a family without the ties of marriage, as has been done on at least one instance (23), courts might not be as sympathetic.

Further, protecting the choice to make a surrogacy arrangement and finding that States are constitutionally required to enforce such agreements are somewhat different propositions. One commentator argues that enforcement of the underlying agreement is important to the viability of surrogacy arrangements, and the State has an obligation to enforce them, lest it unduly interfere with procreative freedom (43).

On the other hand, the unenforceability of prebirth adoption agreements has not prevented couples from using the technique for private adoption. Therefore, failure to enforce surrogacy contracts is not necessarily a direct interference with the right to procreate or even the privilege to adopt. In addition, finding that the genetic father has a constitutional right to obtain custody of his child would be to find that the surrogate mother does not have the same constitutional right to custody. "It would be to assert that the constitutional right of procreation includes within it a constitutionally protected contractual right to destroy someone else's right of procreation," said the New Jersey Supreme Court (21).

Even if States were obligated to enforce the agreements, that enforcement need not necessarily extend to ordering "specific enforcement," i.e., full performance of the agreement to relinquish custody of the child and to terminate the mother's parental rights (14). Assessing monetary damages for breach of contract could be considered a sufficiently strong mechanism for ensuring the general regularity of these arrangements, and should meet any test of a State's obligation to facilitate the use of social arrangements for family formation.

Protecting Children Conceived by Noncoital Techniques

The State has a traditional interest in protecting children from physical harm. Under compelling circumstances, this interest may justify protecting a child from genuine psychological harm as well, as for example when the State forbids child labor, which, while not unhealthful, nevertheless interferes with schooling (35). If children were genuinely harmed by the fact of their noncoital conception, then State efforts to regulate or even ban certain practices might well be held to be constitutional. As procreation is a fundamental right, however, State regulation would have to be narrowly drawn to accomplish its goal of protecting children while minimizing the interference with freedom in procreation.

State protection of children conceived by noncoital techniques might be manifested by regulating access to information concerning genetic and gestational parentage, by regulating or prohibiting surrogacy, or by restricting the kinds of nontraditional adult groups that might be allowed to use these techniques in order to form a family.

With the rapidly increasing usefulness of environmental and genetic information in predicting susceptibility to particular disorders, States might find that children are entitled to have access to medical information about their genetic and possibly gestational parents. Indeed, one commentator suggests that the State has an obligation to provide that such information is gathered for the child, even in light of the fact that some nonadopted children are unaware of their full genetic parentage (1).

Adoptees have long argued unsuccessfully that they have a right to information about their biological parents (38,39), even though some nonadopted children also do not know their full genetic parentage, but scientific developments and the increase in the number of children conceived by artificial insemination might persuade legislatures to provide a recordkeeping system that ensures the transmission of nonidentifying medically useful information. There is little question that such a law would be constitutional.

Release of identifying information is more troubling, as this might override the genetic or gestational parent's desire for privacy. However, if State regulations were prospective—i.e., if these parents were to know at the time they agree to participate in these arrangements that their identity might be revealed—then there seems little question that the State interest in even the psychological well-being of these children could justify making the information available. Research on the psychological effects of having been conceived noncoitally is just beginning (see ch. 15).

States might choose to protect children from custody battles by legislatively adopting a strong presumption of custody with the intended rearing parents—e.g., the genetic father and adopting mother in the case of surrogacy. This would help avoid situations in which a child is moved from one home to another during or following a lengthy custody dispute, but it raises troublesome questions concerning the violation of the surrogate mother's own constitutional rights. Some argue, for example, that enforcing surrogacy contract provisions that deny the surrogate mother parental rights to her child or full control over medical and dietary decisions is tantamount to peonage (32). Peonage, the forced performance of certain personal service contracts when the employee opts to breach (34), is illegal in the United States (18 U.S.C. 1581-1588).

In contrast, States might try to protect children from undesirable custody battles or home arrangements by refusing to enforce surrogacy contracts, thereby allowing the traditional principles of family law to guide judicial decisions concerning maternity, paternity, and custody. Basing custody of a child on a surrogacy contract does not allow a court to make its traditional judgment concerning which home is superior. Such judgments are normally part of any dispute between parents. Further, surrogate matching services generally do not operate as licensed adoption agencies, and therefore do not screen the intended rearing parents (see ch. 14). Thus, automatic enforcement of contract terms concerning custody and termination of parental rights might leave the child without the protection of either adoption agency screening or judicial oversight.

Another possibility for protecting children is to regulate surrogacy arrangements in some fashion that assures adequate homes to the resulting children. However, to the extent that such regulatory efforts are used to screen participants for fitness to be parents, the regulations will raise questions concerning interference with the right to procreate and violation of the 14th Amendment's guarantee of equal protection to all citizens under the law. The fact that no such screening takes place for coital reproduction would be a factor.

To the extent that the right to procreate is viewed as a fundamental right of the individual, any discrimination among types of people must be justified by a compelling State interest. While protection of a child against immediate physical danger would certainly constitute a compelling circumstance, protection against speculative psychological harms attributable to growing up in a nontraditional home probably could not.

Thus, while singles and homosexuals have had limited success in adopting children, as courts have supported agency decisions to place available infants with parents fitting a more traditional model (31), such individuals have had conspicuously more success in obtaining and retaining custody of their own biological children (50). The speculative harm attributed to growing up in a nontraditional family might be sufficient to place existing children in the most certainly favorable home, but it is not sufficient to bar nontraditional parents from forming and maintaining families generally.

Interference with the exercise of a fundamental right is permitted only when accomplished by the least restrictive means possible, narrowly tailored to a specific governmental purpose. Further, even if such harms could be documented in certain cases, a blanket prohibition against any use of noncoital techniques by singles and homosexuals would likely be considered overly inclusive, as it would not distinguish among individuals who could provide a satisfactory home and those who could not. Although not finding a fundamental right to engage in homosexual conduct, one 1988 Federal court decision held that homosexuals as a class may not be subjected to governmental discrimination absent compelling reasons (57).

PROHIBITING COMMERCIALIZATION OF NONCOITAL REPRODUCTION

Even if the right to procreate extends to the use of noncoital techniques, donor gametes, and surrogacy arrangements, the question remains whether the State may prohibit commercialization of these services—i.e., the payment of fees beyond actual and reasonable expenses. Commercial relationships are ordinarily subject to a wide range of Government regulation. Nevertheless, the Court is reluctant to accept limitations on the individual's right to spend money to exercise his or her own individual rights (5) when such exercise does not directly interfere with the rights of anyone else. Prohibitions on commercialization would most likely be based on the need to protect public morality and to avoid the effects of encouraging individuals to view gametes, embryos, mothers, or babies as articles of commerce (36,37).

The sale of sperm has long been tolerated in the United States. Sperm selling seems to be socially acceptable, in part because it generally does not conjure up images of selling a particular, potential human being. In addition, there is no physical risk associated with sperm donation, although the psychological consequences of selling sperm are largely unknown. Sale of ova would probably be tolerated on the same basis if the associated medical risks of laparoscopy or sonography-guided retrieval could be minimized (see ch. 7).

Sale of embryos is more troublesome, however, and has been outlawed by Florida and Louisiana (see ch. 13). Embryo sales raise the specter of choosing the likely characteristics of a child in the way that those seeking artificial insemination can select the characteristics of a sperm donor, but beyond that of being able to select an embryo based on the characteristics of both parents, rather than only one. Further, selecting embryos is viewed by some as closer to selection of living children than is the selection of sperm. Moreover, there is fear that certain characteristics would garner a premium price. The fear is not totally without justification, as two noncommercial sperm banks already advertise that they only accept donors who have superior education or IQ. Another sperm bank is finding that market demands make certain donors unpopular, and as a result is no longer anxious to use donors who are below average height (46).

Protecting public morality against a developing view of the commercial value of certain kinds of human beings is one basis on which restrictive legislation might be proposed. Such legislation

Commercial Sperm Bank's List of Semen Donor Characteristics

DONOR ID#	RACE	BLOOD TYPE	ETHNIC ORIGIN MOTHER/FATHER	HEIGHT	WEIGHT	BODY BUILD	SKIN TONE	EYE COLOR	HAIR COLOR/TYPE	YEARS COLLEGE	OCCUPATION	SPECIAL INTERESTS
#1	Cauc	A -	English/English	6-0	165	Medium	Fair	Green	Brown/Straight	3	Student/Acct	Sports,Fishing,Piano
#6	Cauc	O +	Welsh/German	5-8	145	Medium	Fair	Brown	Brown/Straight	8	Student/Dental	Guitar,Swimming,Read
#7	Cauc	B +	Swedish/English	6-4	210	Medium	Fair	Blue	Brown/Wavy	4	Student/Biol	Water Spts/Piano/Dance
#9 **	Cauc	A -	Czech/Irish-Ger	6-2	195	Medium	Fair	Blue	Blond/Wavy	8	Student/Dental	Tennis/Music/Sailing
#10	Cauc	AB -	Italian/Italian	5-11	190	Medium	Olive	Brown	Brown/Straight	5	Student/Dental	Piano/Sports
#11	Cauc	AB +	European Jewish	5-11	175	Medium	Olive	Brown	Brown/Straight	2	Student/Anthro	Guitar/Raquet Ball
#12	Cauc	O +	Scand/Engl	6-0	155	Medium	Fair	Hazel	Brown/Straight	4	Stu/Real Est	Computer/Tennis/Skiing
#29 (j)	Cauc	O +	Irish-Ger/Czech	5-10	130	Light	Fair	Green	Brown/Wavy	1	Student/BusAdm	Music/Skiing
#33	Cauc	A +	Jewish/Jewish	5-10	165	Medium	Fair	Blue	Red/Straight	1	Student/BusAdm	Tennis/Skiing
#35	Cauc	B +	Irish/Welsh	5-11	170	Medium	Fair	Brown	Brown/Wavy	7	Administrator	Music/Sports/Travel
#37	Cauc	O +	Irish/English	6-3	210	Medium	Fair	Blue	Brown/Straight	10	Student/Med	Contact Sports/Reading
#40	Cauc	AB +	Dutch/Irish	6-2	170	Medium	Fair	Hazel	Black/Straight	2	Student/BusAdm	Racquet Ball/Computers
#41	Cauc	O +	Scottish/Scot	5-10	190	Medium	Fair	Blue	Brown/Straight	6	Student/Anth	Music/Sports/Travel
#42	Cauc	A +	German/Irish	6-1	160	Medium	Olive	Blue	Brown/Wavy	4	Student/Econ	Music/Sports/Reading
#44	Cauc	B -	German/Swedish	5-11	155	Medium	Fair	Hazel	Brown/Straight	2	Student/Intl	Piano/Vocal/Sports
#47	Cauc	O +	Italian/Irish	5-11	115	Light	Fair	Brown	Brown/Straight	3	Student/Psy	Music/Sports/Computers
#49	Cauc	O -	Swedish/English	6-2	168	Medium	Fair	Blue	Blond/Wavy	3	Student/Hist	Reading/Art
#55 (k)	Cauc	O -	Polish/English	5-9	163	Medium	Fair	Blue	Blond/Straight	1	Student/Law	Music/Sports
#63 (i)	Cauc	O +	German/English	6-1	180	Medium	Olive	Brown	Brown/Straight	2	Student/BusAdm	Sports/Fishing
#64 (i)	Cauc	O +	Irish/German	6-0	180	Medium	Fair	Brown	Brown/Straight	1	Student/BusAdm	Wrestling
#67	Cauc	O +	Italian/Irish	5-10	150	Medium	Olive	Brown	Brown/Curly	3	Student/Engl	Guitar/Tennis/Fishing
#68	Cauc	O +	Italian/Engl	5-6	155	Medium	Fair	Brown	Brown/Curly	7	Nursing Ed	Music/Running/Language
#76 (j)	Cauc	O +	English/Irish	5-8	155	Medium	Fair	Brown	Blond/Wavy	2	Student/Soc	Sports/Coins/Autos

Source: Fairfax Cryobank, Fairfax, VA

could take the form of regulation to minimize the development of explicitly eugenic gamete or embryo banks, or of a complete ban on sales, particularly of embryos. If prohibitions on such sales were a direct interference with procreative rights, legislation based on concern for public morality might fail to withstand the strict scrutiny brought to bear upon interferences with the exercise of fundamental rights. As gametes and embryos can be obtained without payment, however, a prohibition on the sale of sperm, eggs, or embryos would not necessarily unduly burden exercise of the right to procreate. Under such circumstances, any rational State policy would be sufficient.

The commercialization of surrogate motherhood poses somewhat different questions. Such arrangements may be justified as freely chosen techniques for forming a family. The contracts are entered into by adults at a time when no baby has yet been conceived, in furtherance of the right to procreate, and it can be argued that States have a constitutional obligation to enforce them. The Michigan appellate court, however, found no constitutional right to employ surrogate mothers, stating:

> While the decision to bear or beget a child has thus been found to be a fundamental interest protected by the right of privacy, we do not view this right as a valid prohibition to State interference in the plaintiffs' contractual arrangement. The statute in question does not directly prohibit John Doe [sperm donor and intended rearing father] and Mary Roe [surrogate mother] from having the child as planned. It acts instead to preclude plaintiffs from paying consideration [money] in conjunction with their use of the State's adoption procedures [citations omitted; explanatory comments added] (11).

The New Jersey Supreme Court came to the same conclusion, distinguishing commercial surrogacy, which it banned, from other forms:

> We find no offense to our present laws where a woman voluntarily and without payment agrees to act as a "surrogate" mother, provided that she is not subject to a binding agreement to surrender her child (21).

The Michigan and New Jersey decisions are premised on the idea that banning payment to surrogates is not a direct interference with the right to procreate, but rather a legitimate State regulation that does not preclude exercising the right to procreate in other, noncommercial forms. If viewed as the latter, any rational State interest could justify the prohibition.

The question may turn on whether there will be any practical ability to find surrogates should payments beyond expenses be banned. Women's self-reported motivations for becoming surrogates usually include noncommercial considerations, such as a desire to help other people, and there are known instances of intra-family arrangements that do not involve payment (see ch. 14). Whether the lack of a large commercial market in surrogates would constitute a direct interference with procreative liberty is difficult to determine without further guidance from the Federal courts.

Even as statements of "rational" State interest, though, arguments based on protecting public morality are generally weak, if only because the harms to society are usually speculative and attenuated. Opponents of commercialized surrogacy might be pleased that the technique finally acknowledges the economic value of women's reproduction, i.e., that "labor" is labor, but at the same time assert that it makes biological mothers into "workers on a baby assembly line, as they try to convert their one economic asset—fertility—into cash for their other children" (25).

The argument that these women have a right to sell their reproductive potential is countered by noting that other sales of the body, whether in prostitution, peonage, or slavery, are prohibited under law when there is broad social agreement that the sale violates basic principles of personhood. These arguments are valuable as part of the political debate, but should surrogacy be seen as one aspect of a constitutionally protected right to procreate, they may not be sufficiently compelling to justify direct State interference or prohibition.

In this case, however, the State rationale is further supported by a history of prohibitions against buying adoptable babies (see ch. 14), because it degrades human life and puts children at risk of being placed in inappropriate homes simply because the occupants were able to outbid a competing set of aspiring parents. The New Jersey Supreme Court's Baby M decision considered this a crucial point:

> There is not the slightest suggestion that any inquiry will be made at any time to determine the fitness of the Sterns as custodial parents, of Mrs. Stern as an adoptive parent, their superiority to Mrs. Whitehead, or the effect on the child of not

> living with her natural mother. This is the sale of a child, or, at the very least, the sale of a mother's right to her child, the only mitigating factor being that one of the purchasers is the father. . . . In surrogacy, the highest bidders will presumably become the adoptive parents regardless of suitability, so long as payment of money is permitted (21).

Undoubtedly the ban on baby-selling in ordinary adoption makes it more difficult for some couples to raise a family, but the limitation has been tolerated in light of the need to protect the interests of the available children. Despite the fact that childlessness is an unhappy affliction for many, there has never been a recognized right to obtain custody of a child.

In surrogacy, however, the child is relinquished to the genetic father by a woman who may be quite sure that working as a surrogate for this particular man is in her own best interests and those of the child. Although reversed on appeal, the *Baby M* trial court considered whether failure to enforce these agreements would interfere with the adult participants' liberty to make contracts:

> The constitutional test is to balance whether there is "a fair, reasonable and appropriate exercise of the police power of the State as to an unreasonable unnecessary and arbitrary interference with the right of the individual to his personal liberty to enter into these contracts . . ." *Lochner v. New York*, 198 U.S. 45 (1905). Legislation or court action that denies the surrogate contract impedes a couple's liberty that is otherwise constitutionally protected. The surrogate who voluntarily chooses to enter such a contract is deprived of a constitutionally protected right to perform services (21).

The trial court's opinion cites *Lochner*, a decision used to strike down laws protecting workers from excessively long hours and excessively low wages (26). It was used in subsequent years to strike down laws prohibiting child labor or unsafe work settings. Subsequent to the New Deal era, the scope of the *Lochner* decision was reinterpreted, to allow the Government to prohibit what it saw as inherently exploitative employment arrangements (53). Essential to those definitions of *exploitative* were sociological observations of class differences between employers and employees, and inherent differences in bargaining power.

If States choose to view the income disparity between surrogates and those who hire them as similar to the inequities they identified during the New Deal, they might have a justifiable interest in refusing to enforce surrogate contracts or regulating their terms to protect all the participants from exploitation and undue bargaining power. This would be sufficient to justify State regulation of surrogacy in order to protect all the parties involved. It is not clear whether it would be sufficient to justify a general prohibition.

Another concern related to recognizing commercial surrogacy is that its practice might lead to a view of women as childbearers for hire and of babies as articles of commerce (16) (see apps. D, E, F). One leading proponent for the constitutional protection of commercial surrogacy speculated that prohibitions on private, paid adoptions might indeed be affected by finding that there is a right to contract for reproductive services:

> Recognition of such a [surrogacy] contract right also raises the question of why contracts to adopt children made before or after conception but before birth would not be valid, nor why parties should not be free after birth to make private contracts for adoption directly with women who want to relinquish their children. The logic . . . is that *persons, at least if married, have a right to acquire a child for rearing purposes*, and may resort to the medical or social means necessary to do so. Although IVF and its variations preserve a genetic or gestational link with one of the rearing parents, the right at issue may not be so easily confined. It may be that the law of adoption needs to be rethought in light of the right to contract for noncoital reproductive assistance (emphasis added) (44).

Traditionally, prohibitions on paying for adoptable babies are based on a collective judgment that certain things simply should not be bought and sold. Prohibitions against buying human organs have been based on the same reasoning (56), with no successful challenge ever mounted to the fact that this interferes with the rights of individuals willing to purchase organs without which they might die. The New Jersey Supreme Court, considering this point in the *Baby M* case, stated:

> There are, in a civilized society, some things that money cannot buy. In America, we decided long ago that merely because conduct purchased by money was "voluntary" did not mean that it was good or beyond regulation and prohibition. Employers can no longer buy labor at the lowest price they can bargain for, even though that labor is "voluntary," or buy women's labor for less money than paid to men for the same job, or purchase the agreement of children to perform oppressive labor, or purchase the agreement of workers to subject themselves to unsafe or unhealthful working conditions. There are, in short, values that society deems more important than granting to wealth whatever it can buy, be it labor, love, or life (citations omitted) (21).

Some assert that surrogacy contracts are not forms of baby-selling as the "money to be paid to the surrogate is not being paid for the surrender of the child to the father. . . .[T]he biological father pays the surrogate for her willingness to be impregnated and carry his child to term" (21). This view is somewhat disingenuous, as fees to surrogates are usually quite minimal unless a baby is delivered at term; miscarriages or a failure to surrender custody do not entitle the surrogate to full fees (22) (see ch. 14).

Even if, however, the fee were one for services rather than for a baby, the transaction overall is one that has the potential to submerge biological ties and a child's interests to monetary and contractual considerations. "The profit motive predominates, permeates, and ultimately governs the transaction," said the New Jersey Supreme Court (21). State regulations forbidding parents to buy and sell custody rights to each other have long been recognized as constitutional. Overall, commercialization of familial rights and duties is one area in which courts have consistently upheld the constitutionality of legislation based both on protecting the interests of the children involved and more generally on protecting societal morals.

Finally, surrogacy is viewed by some as an arrangement that can lead to the exploitation of certain women (see chs. 11 and 14; app. D). Because of the often considerable difference in income between surrogates and those who hire them (see ch. 14), some argue that there is an inherent element of coercion in surrogacy arrangements, even if the surrogate is free of the pressure of an unwanted pregnancy at the time she agrees to enter into the contract.

Coercion may include "situational coercion," in which an outside force such as poverty or illness severely reduces a person's choices (13). A person faced with starvation may choose to work for less than minimum wages; undocumented aliens often do, and while their choice is autonomous, it is not genuinely free. Whether the economic pressures that lead some women to become surrogates for hire rises to the level of situational coercion that justified overturning the *Lochner* decision and instituting minimum wage and worker protection laws in the 1930s and 1940s is a question of both factual inquiry and value judgment. The New Jersey Supreme Court, while recognizing that surrogates give their consent to the arrangement before conception, nevertheless equated surrogacy with traditional baby-selling:

> The essential evil is the same, taking advantage of a woman's circumstances (unwanted pregnancy or the need for money) in order to take away her child, the difference being one of degree (21).

One added factor, beyond economic need, that may need to be considered is that surrogacy may be the most efficient way for women with children to supplement the family income without having to leave home. With this consideration, surrogacy may be viewed as either a welcome or sinister relief from the situational coercion created by the combination of a widespread preference for in-home parental care of small children, coupled with the small proportion of fathers willing to take on that responsibility.

Overall, the legitimacy of State efforts to prohibit commercialization of reproductive materials and services is likely to turn on whether courts view the prohibition as a direct or indirect interference with the right to procreate. If viewed as a direct interference, States would find it difficult to show that a general prohibition is narrowly tailored to prevent specific, concrete harms while interfering only minimally with the exercise of a fundamental right. They could, however, regulate the arrangements to ensure protection of all parties to the contract, and to ensure that an adequate home will be available for the child at birth. If prohibition of paid surrogacy is viewed as an indirect interference, States might successfully assert a rational State interest based on protecting public morality, surrogate mothers, and possibly even the children conceived by these techniques as the justification for forbidding commercialization of reproductive services.

SUMMARY AND CONCLUSIONS

Evaluating noncoital reproductive techniques involves examining the underlying values at stake in procreative privacy. These include freedom of association, freedom to make decisions that drastically affect a person's self-identity, and rights to have intimate relationships with a view toward producing a child. Although the Supreme Court is split on the reach of privacy outside of a heterosexual union, there is no such split concerning privacy within a heterosexual union when that union is aimed at procreation.

The Supreme Court might well conclude that in vitro fertilization and gamete intrafallopian transfer, if conducted within the context of marriage at least (and probably if done in any stable heterosexual relationship), are within the ambit of the right to privacy. Accordingly, only laws aimed primarily at restricting performance to physicians, monitoring the safety and efficacy of the procedures, and ensuring informed consent could be used to regulate these activities.

Where there are public health risks or third parties who may be harmed, stricter regulation or an outright ban might be permissible. Examples might include surrogacy, experimentation on human embryos, and gamete donation. Regulations for artificial insemination by donor or ovum donation could probably also be strict, since they more indirectly interfere with any right to procreate as well as involve another participant—the gamete donor—whose interests are to be considered. Governmental involvement in this area could include regulation of information dissemination to offspring and donors, as well as medical screening.

Prohibiting commercialization of surrogacy or embryo donation may well be constitutional, as it is consistent with earlier traditions outlawing the sale of human organs, babies, or familial rights and duties. In this case, social and legal tradition would probably support legislation specifically premised on a rejection of the commercialization of familial relationships. The validity of this justification will likely turn on the degree of interference that prohibitions on payment are deemed to have on the exercise of the right to procreate.

Photo credit: Washington Stock Photo, Arlington, VA

It is difficult to predict whether the Supreme Court would uphold legislation restricting the use of IVF, embryo transfer, donor insemination, and gamete intrafallopian transfer to traditional families only. To do so requires demonstrating either that the right to procreate is a right premised largely on family privacy, and that nontraditional families do not enjoy this privacy, or that the right to procreate is an individual right that must nevertheless be curbed in certain persons because they pose a compelling danger to their children or society. Historical precedents on these points are mixed, but recent case law indicates a growing acceptance of nontraditional homes.

It is, however, the interests of the resulting children that largely determine the extent of the State's power to regulate or prohibit noncoital reproductive techniques. Indeed, it is precisely the creation of children that distinguishes a decision to procreate from a decision not to procreate. While the latter can be exclusive to an individual couple, since no child will result, the decision to procreate cannot. Whether or not future children can be seen as having rights, society has an obligation to protect them in reasonable ways from foreseeable harms, and States and the Federal Government have some constitutional authority to do so.

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Chapter 13

Legal Considerations:

Artificial Insemination, In Vitro Fertilization, Embryo Transfer, and Gamete Intrafallopian Transfer

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Chapter 13

Legal Considerations:

Artificial Insemination, In Vitro Fertilization, Embryo Transfer, and Gamete Intrafallopian Transfer

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This chapter reviews the legal rights and duties related to a variety of the infertility treatment and circumvention techniques discussed in this assessment. In many cases, the techniques are so new that little or no guidance is available on how the law will be applied. There is, however, a great deal of speculation in the legal literature, along with a wealth of inadvertently and peripherally related legislation and case law based on principles that may have some application in the area of new noncoital reproductive techniques.

The established medical and surgical techniques for treating infertility do not raise unusual legal problems. They fall squarely within the larger area of medical and public health laws, which encompass questions of informed consent and professional standards of practice. Noncoital reproductive technologies, however, challenge traditional legal thinking by introducing two novel factors into human reproduction: the extracorporeal embryo and the child of up to five parents: genetic mother, gestational mother, rearing mother, genetic father, and rearing father.

The conflicting interests of the many parties in noncoital reproductive technologies are difficult to adjudicate. First, some techniques separate the concept of "biological mother," traditionally a unitary term, into two component parts: the genetic mother and the gestational mother. Existing legal models of the role of the purely genetic connection between parent and child have been worked out in the context of fathers, not mothers. For example, a genetic connection between a man and a child will render him legally and financially responsible for the child, absent a formal legal intervention such as adoption (17,38). The intentions of the man to produce offspring or not are irrelevant.

This legal outcome protects the interests of the child, and explains the one general exception to this rule, i.e., that a child born to a married woman is presumed to be the child of the woman's husband, regardless of the genetic realities of the situation. This "presumption of paternity" is common in State legislative codes (9,45). Provided that the child has two parents, the law will then consider other interests, such as sanctity of marriage, when adult responsibilities for child care are allocated. Note that the emphasis on genetic relationships with men is based on the self-evident fact that men are incapable of any other sort of "biological" relationship.

Similarly, a fairly coherent body of law outlines the rights of "biological" versus "rearing" mothers in the context of adoption (17). Never before, however, have the component rights and responsibilities associated with gestational versus genetic relationships been delineated, let alone balanced against those of social mothers and fathers. Models of responsibility based on male biological linkages may well be inadequate to cover the complexities of female biological linkages, which can entail a gestational relationship as well as one based on genetics.

A second problem is that many of these techniques involve extracorporeal gametes or embryos. The still imperfect national consensus on the status of unborn children affects reproductive technologies, as questions arise concerning the management of unimplanted embryos. Whereas the abortion issue is complicated by the right of an adult woman to control the physical state of her body, the extracorporeal fertilized egg raises the narrower issue of embryo rights. If such rights are found to exist by virtue of the U.S. Constitution or are created by legislative action, then the course of reproductive biology research and treatment will be profoundly affected by limitations on actions that might harm an embryo.

Finally, new reproductive technologies raise a host of issues that are familiar to the law, but that rarely have been seen in such a tangled combination. These include equal access to reproductive services by the poor, the unmarried, and the homosexual; the rights of children with respect to their biological and social parents; the use of contractual arrangements to govern parental relationships; and the role of governmental and commercial interests in areas typically viewed as private. The arrangements facilitated by noncoital reproductive techniques invite a fresh consideration of the legal significance of genetic and social connections between parent and child, and also invite a review of the legal obstacles to the formation of nontraditional family groupings.

This chapter summarizes the legal issues raised by the use of artificial insemination, in vitro fertilization (IVF), embryo transfer, and gamete intrafallopian transfer (GIFT). These techniques have in common the possibility of an extracorporeal embryo or the use of sperm or egg donors. Situations in which a woman gestates a child with the intention of relinquishing her parental rights at birth are examined in chapter 14. Overarching constitutional issues concerning the right to procreate, personal autonomy, the commercialization of procreation, and nondiscriminatory access to noncoital reproductive techniques are discussed in chapter 12.

STRUCTURE OF APPLICABLE LAW

Both Federal and State law will affect the status of noncoital reproductive technologies. The Federal Government has limited powers, i.e., only those powers granted by the U.S. Constitution, with all residual powers falling to the States or the people (10th Amendment). As a result, States generally have the authority by judge-made law (also known as common law) or by State legislation to protect the public health, safety, and morals. It is on this basis that States have the authority to regulate familial relations, including marriage, divorce, adoption, inheritance, and parental duties.

In addition, contracts are generally regulated by State statute. Thus, contracts to arrange for a surrogate mother would be subject to State law rules governing interpretation or enforceability of the agreement. As each State is free to write its own laws, a contract may have differing degrees of enforceability from State to State (32). Some States may consider certain contractual arrangements as entirely void because they are contrary to public policy, such as, for example, a contract of marriage between an adult and a minor. Another State might consider the contract voidable, i.e., the contract may be voided upon request of one of the parties. In many cases, the request to void a contract may come only from the vulnerable party to the transaction, in this case the minor. Finally, some States may find no public policy reason to treat a contract in any special way, and therefore hold the contract enforceable according to the general laws of the State.

The distinctions made among void, voidable, and enforceable contracts are important in the context of surrogate motherhood arrangements, which may offend public policy in some States. Others might view either the surrogate mother or the infertile couple as a particularly vulnerable party who may initiate an action to void the contract. Thus, the enforceability of these contracts will likely vary around the country. Even with a definitive statement from the Federal courts that part or all of these transactions are constitutionally protected, individual State regulations may differ considerably.

Another applicable section of State law is known as torts, which governs most noncontractual situations in which someone harms another. The two most important areas of tort law cover intentional harms—e.g., intentionally touching someone's body without consent—and unintentional harms. Often the latter are caused by negligence, which occurs if someone behaves in an unreasonable way that breaches a duty of care owed to someone else, and thereby causes harm. A relevant example would be a physician mistakenly removing a healthy ovary rather than a diseased ovary scheduled for removal. After having the diseased ovary removed, the woman could sue for damages to compensate for the additional surgery, for the resulting infertility, and for her pain and suffering.

Federal law can touch on some of these same issues if the activity involved is partly or wholly funded by Federal monies. A hospital, for example, though regulated by a State Department of Health, may also be subject to conditions on any Federal money it receives through Medicare or Medicaid. These conditions on the receipt of Federal money are a kind of Federal regulatory mechanism. The Federal Government also has the power to regulate interstate commerce. A physician may be subject to State licensure and discipline laws, but if the physician opens up a nationwide business with many offices, the business itself may be subject to Federal regulations. This commerce power of the Federal Government has been interpreted liberally in recent years, and can serve as the basis for extensive regulation when an activity is interstate in nature, or when it has an effect on interstate commerce (76).

Not only can Federal regulatory powers affect the operation of a State activity, but Federal constitutional protections may affect the structure of State laws. For example, a State law regulating adoption may specify that single-race homes are to be given preference to mixed race homes when placing children. Federal constitutional guarantees of equal protection under the laws, however, may void such a requirement as unreasonably discriminatory (76). This and other aspects of Federal constitutional law affecting the limits of permissible State legislation concerning reproductive technologies are discussed in chapter 12.

In general, Federal constitutional law is superior to Federal statutory law, which in turn is generally superior to State statutory or common law if there is a direct conflict (33). State constitutions, however, can go further than the Federal constitution in their protections, and thus form a separate basis for attacking a State law as discriminatory, even if the Federal constitutional interpretations find the law nondiscriminatory (76).

A lawsuit based on an area of State law, such as contract, tort, or family law, will generally be heard in a State court. However, if the parties to the litigation come from different States and if more than $15,000 is at stake, a Federal court may hear the case (33). This does not mean that Federal law will be applied to the case; Federal common law on these topics generally does not exist (31). Rather, the Federal court will determine which State's laws ought to apply, using the principles of "choice of law" (47). The decision is not a trivial one, as certain activities may be governed in entirely different ways in one State or another. For example, the practice of surrogate motherhood is now interstate in nature, with surrogates and intended social parents often coming from different States. In the event that one State were to explicitly legalize surrogate motherhood and another to forbid it, choice-of-law principles might determine the outcome of a Federal court's decision with respect to a surrogacy contract.

ARTIFICIAL INSEMINATION BY HUSBAND

Artificial insemination by husband commonly refers to artificial insemination in which the semen is provided by the recipient's partner, whether or not she is married to him. This form of insemination is relatively uncomplicated legally because no third party is involved; the sperm donor is the intended parent of the child. Nevertheless, certain problems can arise, for example, with respect to disposition of sperm left frozen after a man's death. Furthermore, artificial insemination by husband may be subject to State law requirements that a physician perform the insemination. Finally, cryopreservation of semen may lead to physician or laboratory liabilities when storage facilities are not properly managed.

Improper Handling of Sperm

Negligent handling of sperm can give rise to professional liability if it causes harm. Further, to the extent that sperm are the property of a man, with a physician storing or using them as per the man's directions, a physician could be viewed as a bailee, i.e., someone charged with the responsibility of caring for the property of another (59). In this capacity, the physician once again must be reasonably careful. Damages, however, are likely to be quite small for any loss of sperm or sperm viability, as the sperm can be replaced at little expense and without dangerous or invasive procedures.

One exception is the loss of irreplaceable sperm —e.g., sperm stored prior to irreversible sterilization. In 1987, suit was brought by a couple whose frozen sperm was damaged during transit from the cryobank to the site of insemination. The husband, who had stored the sperm before undergoing radiation and chemotherapy, could not replace the semen, and sued for his irrevocable loss of ability to genetically parent a child (81).

If the sperm is lost after the death of the husband, and the widow seeks damages for the loss, the damages might also be high, as the loss is again irrevocable. In this case, however, the widow would have a right to recovery by virtue of her entitlement to her husband's property; if sperm are not considered "property," she may have no right to recover at all.

Disposal of Sperm After Husband's Death

No State statutes specify whether frozen sperm remaining after a man's death are to be considered property of the estate, thereby passing to heirs by his will or by State law. Nor are sperm clearly considered property of the widow, to be used for impregnation or destroyed, per her request, or as abandoned property reverting to the institution or the State. In the only case to date on this subject, a French woman successfully sued in French courts to recover her late husband's sperm in order to bear a child of his. The court declined to consider the sperm as an object of a commercial contract, or as a donated organ subject to existing French regulations. Rather, it said that sperm deposition created an obligation for conservation and restitution, and that the widow's family established "without equivocation the formal will of Corinne's husband to make his wife the mother of a common child, whether the conception of this child happened while he was living or after his death" (26).

Assuming that a woman uses the frozen sperm of her late husband in order to have a child by him, a problem develops with respect to the "after-born" child—one born after the death of his or her parent. Ordinarily, after-born children are the legal offspring of the deceased parent, entitled to inherit along with the rest of his children. In this case, however, the child is not only born but conceived after the death of its genetic father. Considering such children as the legal offspring of the deceased father creates a number of trust and estate difficulties, most of which are purely internal aspects of State law and beyond the scope of this report (49,75).

One obvious problem is that it makes ambiguous the typical language "to my children" as used in wills. The possibility of an after-conceived child would make this class of children open to additions much longer than the current 9 months following death, thus making it impossible to probate a will expeditiously. Similar problems could arise with respect to frozen embryos, with the death of one or both genetic parents no longer an insuperable obstacle to bringing the child to term.

Louisiana law, which touches on the subject of inheritance rights of IVF embryos, states that the embryo will have such rights at the time of its birth. The law places no time limit on this right, and so opens the way for inheritance rights in children whose fathers have died many years before they were brought to term.

ARTIFICIAL INSEMINATION BY DONOR

Sperm donation—the oldest of noncoital techniques—has existed as a therapeutic option in the United States since about 1950 and has resulted in statutes in some 30 States (see table 13-1). Of these, eight appear to be modeled on the Uniform Parentage Act. Others share some common lan-

Table 13-1.—State Statutes—Artificial Insemination

State	Has laws on artificial insemination	Physician must inseminate	Refers only to married women	Mentions husband consent	Legitimates offspring	Requires recordkeeping	Limits number offspring per donor	Requires screening for disease
Alabama	x	x	x	x	x	x		
Alaska	x		x	x	x			
Arizona								
Arkansas	x	x	x	x	x			
California	x	x		x	x	x		
Colorado	x	x			x			
Connecticut	x	x		x	x	x		
Delaware								
District of Columbia								
Florida	x			x	x			
Georgia	x	x			x			
Hawaii								
Idaho	x	x		x	x	x		x
Illinois	x	x		x	x			
Indiana								
Iowa								
Kansas	x			x	x	x		
Kentucky								
Louisiana	x				x			
Maine								
Maryland	x		x	x	x			
Massachusetts								
Michigan	x		x	x	x			
Minnesota	x	x			x			
Mississippi								
Missouri								
Montana	x	x	x	x	x	x		
Nebraska								
Nevada	x	x	x	x	x	x		
New Hampshire								
New Jersey	x	x			x			
New Mexico	x	x		x	x	x	x	
New York	x	x	x	x	x			
North Carolina	x			x	x			
North Dakota								
Ohio	x	x		x	x	x		x
Oklahoma	x	x		x	x	x		
Oregon	x	x		x	x	x		x
Pennsylvania								
Rhode Island								
South Carolina								
South Dakota								
Tennessee	x		x	x	x			
Texas	x		x	x	x			
Utah								
Vermont								
Virginia	x	x	x	x	x			
Washington	x	x		x	x	x		
West Virginia								
Wisconsin	x	x		x	x	x		
Wyoming	x	x		x	x	x		

SOURCES: Ala. Code. Sec. 26-17-21 (Supp. 1986); Alaska Stat. Sec. 25.20.045 (1983); Ark. Stat. Ann. Sec. 61-141 (c) (1971); Cal. Civil Code Sec. 7005 (West 1983); Cal. Penal Code Sec. 270 (West Supp. 1987); Col. Rev. Stat. Sec. 19-6-106 (1986); Conn. Gen. Stat. Ann. Sec. 45-69 (f-m) (West 1981); Fla. Stat. Ann. Sec. 742.11 (West 1986); Ga. Code Ann. Sec. 43-34-42 (Michie 1984); Ga. Code Ann. Sec. 19-7-21 (Michie 1982); Idaho Code Secs. 39-5401 to 39-5408 (1985, Supp. 1986); Ill. Ann. Stat. ch.40, paras. 1452-1453 (Smith-Hurd 1987); Kan. Stat. Ann. Secs. 23-128 to 130 (1981, Supp. 1986); La. Civ. Code Ann. art. 188 (West Supp. 1987); Md. Est. & Trusts Code Ann. Sec. 1-206b (1974); Md. Health Gen. Code Ann. Sec. 20-214 (1987); Mich. Comp. Laws Secs. 333.2824 to 700.111 (West 1980); Minn. Stat. Ann. Sec. 257.56 (1987); Mont. Code Ann. Sec. 40-6-106 (1985); Nev. Rev. Stat. Sec. 126.061 (1985); N.J. Stat. Ann. Sec. 9:17-44 (West Supp. 1987); N.M. Stat. Ann. Sec. 40-11-6 (1986); N.Y. Dom. Rel. Law Sec. 73 (West 1977); N.C. Gen. Stat. Sec. 49A-1 (1984); Ohio Rev. Code Ann. Secs. 3111.30-.38 (Page Supp. 1986); Okla. Stat. Ann. tit. 10, Secs. 551-553 (West Supp. 1985); Or. Rev. Stat. Secs. 109.239-.243, and 109.247 (1985); Or. Rev. Stat. Secs. 677.355-677.370 (1985); Tenn. Code Ann. Sec. 68-3-306 (1987); Tex. Fam. Code Ann. Sec. 12.03 (Vernon 1986); Va. Code Ann. Sec. 64.1-7.1 (1986); Wash. Rev. Code Ann. Sec. 26.26.050 (1986); Wis. Stat. Ann. Sec. 767.47 (West 1981); Wis. Stat. Ann. Sec. 891.40 (West Supp. 1987); Wyo. Stat. Sec. 14-2-103 (1936).

guage, but vary widely in their precise wording, ranging from a detailed code to a terse statement of their intended legal effect.

Despite the variation in wording, all artificial insemination by donor statutes make clear that the offspring of donor sperm shall be treated as the legal offspring of the consenting husband for legitimacy, inheritance, and support purposes (28,40,41,57). Sometimes the legal implications are directly specified; in other cases they arise by implication from designation of the offspring as the natural or legitimate child of the consenting husband. Sometimes this effect is certain only if the precise statutory conditions are satisfied, leaving open the consequences if statutory conditions concerning physician, marital status, and the like are not met. The result is that many questions are not answered by clear statutory language, leaving the parties to act on legal predictions of varying certainty.

The artificial insemination by donor laws appear to follow and implement a contractual approach to offspring status when donor, recipient, and recipient's husband agree that the husband shall assume all rearing rights and duties and the donor none. It may be that this model will be followed for donor sperm transactions that do not follow all statutory specifications, for artificial insemination by donor in States without specific legislation, and for egg and embryo donation as well, though this will depend on court interpretation and future legislation.

Although these statutes operate to legitimate offspring of donor sperm, they fail to grapple with a number of potential problems discussed in this section, such as limiting the number of offspring per donor, screening for infectious and genetic diseases, clarifying the legal consequences of use by a single woman, and maintaining adequate records.

Physician Requirement

Twenty-one[1] of the thirty artificial insemination by donor statutes provide that offspring are the legitimate children of the consenting husband when the insemination is done by a "licensed physician," "certified medical doctor," or person "duly authorized to practice medicine."

In States with this specification, the legal effect of insemination by someone other than a physician, such as husband, lover, donor, friend, family member, or even medical technician, nurse, or physician's assistant, may be uncertain. States such as Ohio avoid this confusion by stating explicitly that failure to have insemination performed under the supervision of a physician will not prevent the child from benefiting from the law's legitimization provisions. This would probably be the result obtained by judicial decision in States without such clarifying language (48).

Ambiguities in the statutes raise questions as to whether inseminations done without the required physician supervision have different legal consequences (43). For example, in the *Jhordan C.* case, the lack of physician-supervised insemination was one factor that persuaded the court to permit the sperm donor to have visitation rights. That case was complicated, however, by the fact that the mother was unmarried but living with another woman who also was to have visitation rights.

In the nine States that do not specify physician insemination, State laws against the unauthorized practice of medicine might nevertheless make it criminal for third parties to inseminate. In Georgia, Florida, and Idaho it is specifically a crime for someone other than a physician to do the artificial insemination. Nevertheless, these laws would not affect the enforceability of the parties' agreement concerning rights and duties toward the offspring.

The reasonableness of State laws that directly or indirectly require a physician to perform artificial insemination is questionable. The technique itself can be quickly learned and needs no special equipment. Limiting vendors who screen semen from anonymous donors to those with medical expertise may be easily justified (see ch. 9); similarly limiting those who use this screened semen for themselves alone is more difficult to rationalize.

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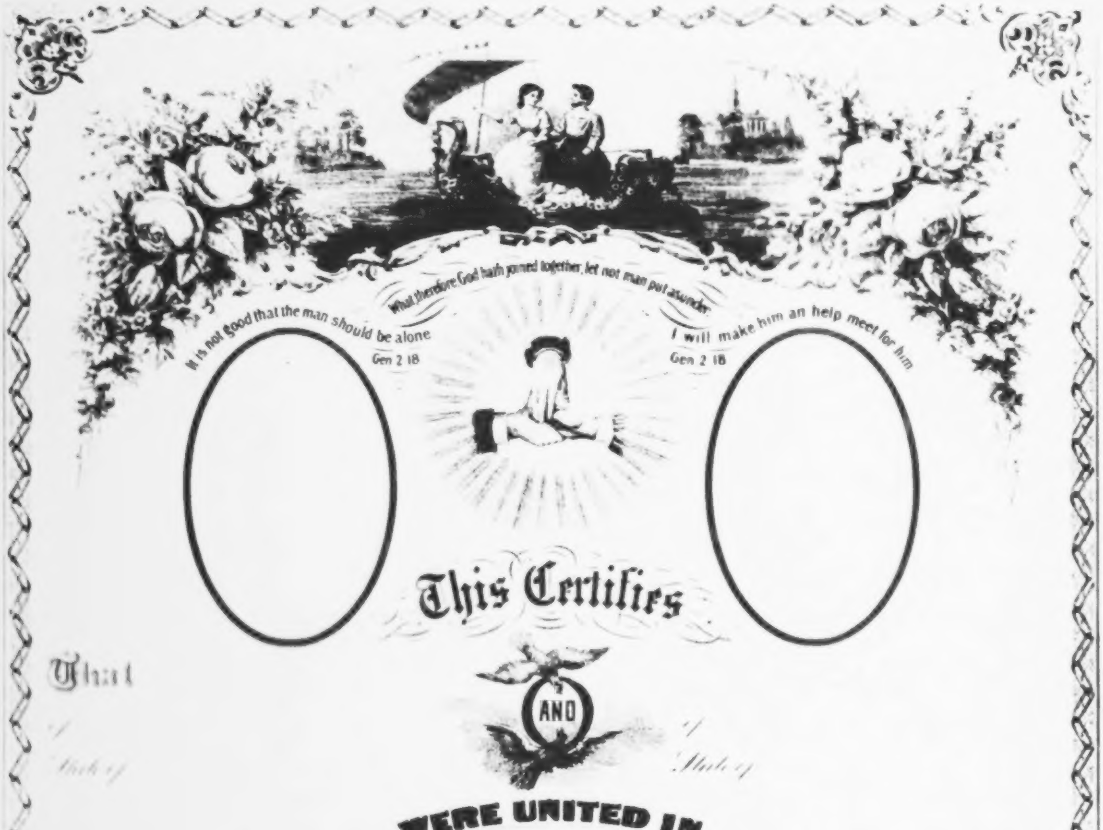
[1] Alabama, Arkansas, California, Colorado, Connecticut, Georgia, Idaho, Illinois, Minnesota, Montana, Nevada, New Jersey, New Mexico, Ohio, Oklahoma, Oregon, Virginia, Washington, Wisconsin, Wyoming.



What therefore God hath joined together, let not man put asunder

It is not good that the man should be alone
Gen 2 18

I will make him an help meet for him
Gen 2 18

This Certifies

That

AND

of

State of

of

State of

WERE UNITED IN

HOLY MATRIMONY

According to the Ordinance of GOD and the Laws of the
STATE of at on the
day of in the year of Our Lord
One thousand Eight Hundred and

Marriage is honourable in all
Heb 13:4

Witnesses

Photo credit: Library of Congress

Nineteenth Century Marriage Certificate

Marital Status of the Recipient

No statute explicitly makes it illegal for an unmarried woman to be artificially inseminated. However, most State artificial insemination by donor laws, directly or by implication, address the status of offspring where the husband consents to the insemination, thus leaving open the question of how the statutory provisions will have effect if there is no husband. When a consenting husband is present, these statutes cut off the sperm donor's rights of fatherhood and grant them instead to the consenting husband. Not all statutes are as clear as that of Ohio, which provides that even if no husband is present, sperm donor's rights and responsibilities will be cut off automatically. Another question is whether the sperm donor may sue to have these rights and responsibilities reinstated. Donors known to the recipients have successfully sued for rights of fatherhood when no husband is present (20,43).

Requirements for Consent of Recipient's Husband

All the statutes require that the husband consent for the offspring to be treated as his legitimate or natural child and for him to take on rearing rights and duties. Some States specify that the consent be in writing, four require that it be signed by both husband and wife (Alabama, California, Illinois, Ohio), and several States require that it be filed confidentially with the State health department. The penalty for failure to obtain the husband's consent is often unclear.

Husband's Rights and Duties to the Child

The only possible exceptions to the husband being the legal father of the resulting child may be in situations in which the recipient failed to obtain her husband's consent, as previously discussed, or when the recipient is in fact planning to relinquish the child to the genetic father (i.e., the recipient is a surrogate mother). In the latter case, a contractual agreement ordinarily purports to rebut the presumption of paternity or to exempt the parties from the statutory legitimation of the artificial insemination by donor laws. Whether such a contractual effort works will depend on the particular laws of the States in which the parties reside, and whether surrogate parenting contracts will be recognized by those State courts (see ch. 14).

Legal Status of Resulting Children

The offspring's status as the natural or legitimate child of the consenting husband brings into play the State law concerning rights and duties that fathers owe their natural or legitimate children, and affects the offspring's right to support and inheritance. With artificial insemination by donor, this status means that the consenting husband is listed on the birth certificate and has rearing rights and duties. The offspring inherits through him either by will or intestacy laws and not through the donor. The donor loses explicitly or by implication of law the usual rights and duties of a natural father.

Requirements for Consent of Donor's Wife

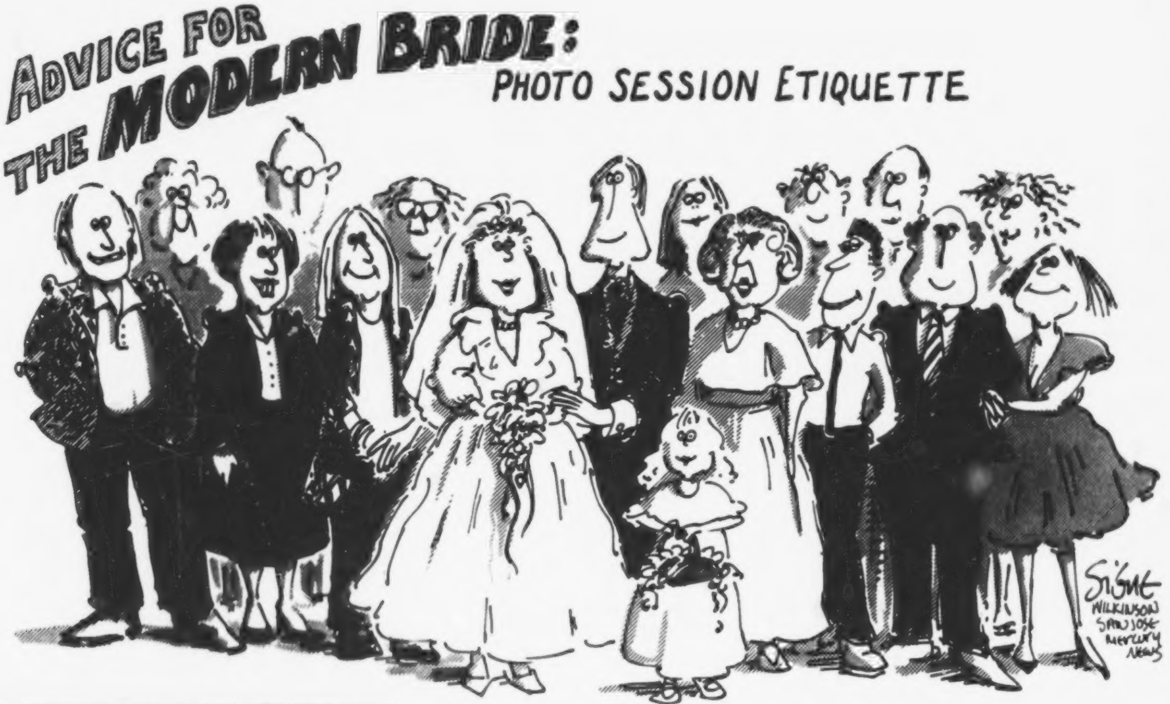
None of the 30 artificial insemination by donor statutes require a man to obtain his wife's consent before donating sperm, and thereby committing an act intended to produce offspring outside the context of his marriage. This stands in contrast to the requirement that a wife obtain her husband's consent before undergoing artificial insemination, required by every statute (9). One rationalization for the distinction is that the sperm donor will probably not be legally or financially responsible for the offspring, at least if he does not subsequently seek recognition as the father of the child.

Sperm Donor's Rights and Duties to the Child

By direct statement or clear implication, all 30 State artificial insemination by donor laws remove from the donor any rearing rights and duties to the offspring when the statutory provisions are met. Sometimes this is stated directly; sometimes it occurs by clear implication from recognition of the consenting husband as legitimate or natural father. Presumably this is the donor's wishes in those cases as well, thus implementing the contractual agreement among the parties. This arrangement helps to ensure an adequate supply of donors, for otherwise each would be subject to an unknown number of claims on his financial and emotional resources at some indeterminate time in the future.

The situation can be different, however, in the case of a known sperm donor. In the New Jersey case of *C.M. v. C.C.*, a man provided sperm to his still virginal fiancée, who desired a child by him prior to marriage. After the birth, the engagement was broken off. The father sued for visitation rights, which were contested by the mother. The court held that in the absence of another male parent for the child, and in light of conflicting evidence of the parties' original intentions, it was in the best interests of the child and of the State to preserve a two-parent arrangement, even if the parents were unmarried (20).

Decisions such as these demonstrate the strength of the judicial interest in ensuring two legal parents to a child born as a result of artificial insemination. They also explain, however, the reason for the demand for anonymous artificial insemination by donor among single and lesbian women. Obtaining sperm from a friend rather than from an anonymous donor means that there always exists the possibility of continued involvement by this friend in the lives of the mother and child, or even of a custody battle (43). Yet for these women the very reason for using artificial insemi-


ADVICE FOR THE MODERN BRIDE:
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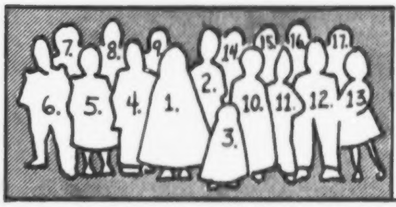

1. Bride 2. Groom 3. Groom's daughter from first marriage 4. Bride's mother 5. Bride's mother's current lover 6. Bride's sperm donor father 7.&8. Sperm donor's parents who sued for visitation rights to bride 9. Bride's mother's lover at time of bride's birth 10. Groom's mother 11. Groom's mother's boyfriend 12. Groom's father 13. Groom's stepmother 14. Groom's father's third wife 15. Groom's grandfather 16. Groom's grandfather's lover 17. Groom's first wife

SOURCE: Signe Wilkinson, Philadelphia Daily News (from San Jose Mercury News).

nation by donor is to avoid such entanglements. Thus, use of sperm banks and anonymous donors remains the surest way for such women to achieve pregnancy without requiring a sustained involvement with a man. This fact brings into focus why physician reluctance to provide artificial insemination by donor services to singles and lesbians poses such a troubling dilemma to these women.

An important question left open by most artificial insemination by donor laws is whether parties may actually agree in advance that the donor will have rearing rights and duties toward the offspring. This will be of special importance when the donor is providing the sperm as part of a surrogate arrangement, whereby the donor and his partner will have a child to rear who is genetically related to the donor. One Arkansas statute does provide for this eventuality (see ch. 14). It will also be important when the recipient is unmarried and wishes to share parenting rights and duties to some limited extent with the donor.

Although most statutes do not provide for the latter contingency, New Jersey, New Mexico, and Washington specifically allow the donor and recipients to provide that the donor will have such rights and duties as the parties agree on. However, it is not clear that the parties will be able to change legitimacy and inheritance implications of artificial insemination by donor when a consenting husband is present, even if they may agree not to omit the donor altogether from rearing rights and duties. Even the New Mexico statute has some ambiguity, as it does not directly address the possibility that the recipient in this case is married, with a consenting husband who wishes to share in recognition of the child.

Professional Responsibility for Screening Sperm

Only 3 of the 30 State statutes address donor screening. Idaho and Oregon have statutes directed at the donor, making it a violation or crime for a man to become a donor if he knows he has a venereal or genetic disease. Ohio's statute requires a full physical examination and a medical and genetic history, and includes a list of suggested tests for specific infectious and genetic diseases. Generally, however, the artificial insemination by donor statutes do not address a physician's duty to screen donors to prevent transmission of venereal or genetic diseases to the recipient and to offspring. Only Idaho and Ohio require physicians to quarantine frozen semen and to screen the donors for human immunodeficiency virus (HIV).

A 1978 survey indicated that many physicians were inadequately screening donor sperm for genetic and sexually transmitted diseases (23). This survey sparked a flurry of journal articles and conference discussions on ways to improve screening practices and to avoid liability for poor screening (6,7,8,13,14,51,65). Physicians and sperm banks have somewhat improved their screening practices, particularly with respect to sexually transmitted diseases (80). For example, the vast majority of sperm banks now quarantine sperm while doing followup testing on a donor (64,80). This is important for identifying donors who are seropositive for HIV antibodies, as such results may show up months after the donor was capable of transmitting the virus through his semen (see ch. 9).

In general, physicians are held to reasonable standards of care in their screening for genetic and sexually transmitted diseases. "Reasonable" is a flexible term in the law, and in this case would reflect that level of care common among similarly situated professionals. Failure to exercise such care would be malpractice, and could leave the physician liable for the physical and emotional harm resulting from the transmission of the disease (see ch. 9). For example, in 1987 a California woman brought suit claiming that she suffered from cytomegalovirus (CMV), a mild disease in adults but one that can cause birth defects in children, as a result of using semen from a sperm bank that screened for many infectious diseases but not for CMV (15,83). A court would be free to evaluate whether the sperm bank's screening protocols were "reasonable."

The American Association of Tissue Banks and the American Fertility Society (AFS) have issued guidelines on gamete donation and operation of sperm banks (1,3,5), and the American College of Obstetricians and Gynecologists endorsed the AFS guidelines (2). Such guidelines are voluntary, but may be considered strong evidence of at least a minimal level of professional responsibility for screening, should a court consider a malpractice claim on these grounds. However, adherence to these standards is not necessarily evidence of reasonably prudent practice of medicine; courts have at times found that an entire industry or professional group has been failing to meet such a standard (see ch. 9).

The AFS guidelines, for example, did not until 1988 recommend that all use of fresh sperm be discontinued, even though only frozen, quarantined sperm can be eventually judged certain to be incapable of transmitting HIV. Instead, the 1986 AFS guidelines proposed a series of careful steps to be taken to help judge whether a donor poses any risk. The AFS guidelines are periodically reviewed, and were amended in early 1988 to express a preference for the use of frozen, quarantined semen only (58); past guidelines made no such recommendation. Should someone have contracted acquired immunodeficiency syndrome (AIDS) from fresh semen donated in accordance with the previous AFS standards, a court would be free to evaluate whether those procedures were in keeping with then-common practice and reasonably prudent. This determination could well be affected by recent reports that at least two sperm banks have had donors "seroconvert" during the quarantine period—i.e., donors tested positive for exposure to HIV soon enough after having donated sperm that it is possible they were infectious at the time of donation (66,69,83) (see ch. 9).

In early 1988, the Centers for Disease Control, coordinating with the Food and Drug Administration, recommended that all donor semen should be frozen and quarantined, so that donor testing for HIV could take place both at the time of donation and 6 months later (see ch. 9). A physician's failure to comply with this Federal recommendation would probably be considered negligent by a court. Compliance would not necessarily preclude a finding of negligence (see ch. 9), but would be strong evidence of reasonable practice.

A sperm donor who fails to report a genetic or infectious disease that might harm the recipient or child may well be violating a common-law duty of care to these parties. The general lack of recordkeeping in current artificial insemination by donor practices makes it impossible for most recipients to trace their donors in order to complain of such behavior, but should that situation change, sperm donors might conceivably find themselves responsible for deliberate or negligent misrepresentation of their health. For example, in the California suit over CMV infection via artificial insemination, the plaintiff sought a court order to open the sperm bank's records in order to identify the sperm donor, who has been included as a defendant in her suit. Although the California court hearing the case denied the request, similar suits could be brought in other jurisdictions.

Recordkeeping and Confidentiality

Fourteen[2] State artificial insemination by donor statutes specify that the written consent of the recipient and her husband be filed with the State health department, to be kept confidential except in response to a court order. A few States, such as Ohio, require the physician to keep the signed consent forms sealed and confidential rather than file them with the State. In some cases the registration requirement applies only after the birth of the child. The inseminating physician is required to file the forms only if the physician is aware of the birth, which may not occur if another physician delivers the baby. Thus some States make clear that failure to follow the recordkeeping provisions does not affect the allocation of rearing rights and duties otherwise recognized in the statute.

Adoptees have argued that a person has a right to know the identity of his or her biological parents (60), claiming that issuing birth certificates with adoptive parents' names unconstitutionally discriminates against adoptees, and violates their right to privacy (see ch. 12). Their arguments have been unsuccessful, so it seems unlikely that children conceived with anonymous donor sperm will have any more success objecting to procedures to guard the identity of their genetic fathers. Further, identification of the donor's identity may discourage many men from offering to become sperm donors, thus reducing the supply of semen for artificial insemination. However, many States have passed legislation to provide adoptees with nonidentifying information concerning the health, interests, and ethnic background of the biological parent (61), and such statutes could be held to apply or be extended to cover children of sperm donor fathers.

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[2] Alabama, California, Connecticut, Idaho, Kansas, Montana, New Mexico, Nevada, Ohio, Oklahoma, Oregon, Washington, Wisconsin, Wyoming.

IN VITRO FERTILIZATION

Although used in an estimated 169 programs nationwide, little statutory regulation exists on IVF. Only two State statutes, those of Pennsylvania and Louisiana, explicitly address therapeutic IVF. Fetal research statutes do not appear to have much of an impact, despite broad language in some that might be deemed to apply to embryos (see apps. C and F). There seem to be no statutory restrictions on IVF with egg and sperm provided by the intended social parents. Couples probably have a legal right to resort to IVF or to donate embryos to others, and, except in Louisiana, to discard unwanted embryos. They also appear to face no legal barriers, other than restrictions on research, to freezing their own embryos for later use by themselves.

Control Over Disposition of Embryos

States with laws regulating fetal research use terms such as "embryo," "product of conception," and "unborn child" that could be read to include preimplantation embryos (see table 13-2), raising the question of whether the statutory use of these terms might restrict clinical use of IVF and any of its variations. Further, five States have now adopted laws aimed specifically at IVF research or therapeutic applications (see box 13-A). At issue is whether any legal constraints prohibit couples:

- from using basic IVF to initiate pregnancy,
- from deciding not to transfer all the embryos to a uterus,
- from cryopreserving and thawing embryos for later transfer, or
- from donating embryos to willing recipients.

Fetal research statutes, many of which address questions of research with aborted fetuses, do not generally speak to these issues. For example, they do not appear to prohibit clinical use of IVF. First, most apply only to aborted embryos or fetuses, and not to preimplantation embryos. Second, they ban research or experimentation, not nonexperimental therapeutic applications of techniques that aim at bringing healthy offspring into being. (See ch. 9 for discussions of the status of IVF as experimental or therapeutic, and of State and Federal limits on embryo research.) Nor would the statutes clearly ban cryopreservation of embryos, as enabling embryos to be transferred during a later cycle may fall within the statutory exceptions for research done to benefit or avoid harm to embryos.

Finally, the validity of fetal research statutes remains to be determined; in the only challenge to date, a Louisiana ban on experimentation with fetuses obtained from induced abortions was struck down for vagueness (50). In its decision, the Court focused on the fact that it is difficult to distinguish between experimentation on the fetus, and tests on the fetus that are necessary for ensuring maternal health. As a result, physicians would be unsure of whether their actions were banned by the statute. Adoption of this reasoning by other courts would make it unlikely that statutory bans on fetal experimentation, unless quite narrowly drawn, could survive constitutional challenge.

A concurring opinion in this case focused on the unsubstantiated distinction between fetal tissue obtained by induced abortion and fetal or otherwise human tissue obtained from different sources. (A concurring opinion is a separate opinion written by a judge of the court who agrees with the outcome of the case, in this case, striking down the Louisiana statute, but who prefers alternative reasoning.) Finding no rational reason to ban experimentation on fetal tissue derived from induced abortion while at the same time allowing experimentation on corpses and fetal tissue derived from miscarriages, the concurring opinion concluded that the statutory ban was part

Table 13-2.—State Statutes—Fetal Research

State	Restricts fetal research	Prohibits sale of fetus or embryo	Mentions preimplantation embryos[a]	May restrict research with pre-embryos[b]
Alabama				
Alaska				
Arizona	x		x	x
Arkansas	x	x		x
California	x		x	x
Colorado				
Connecticut				
District of Columbia				
Delaware				
Florida	x	x		x
Georgia				
Hawaii				
Idaho				
Illinois	x		x	x
Indiana	x			
Iowa				
Kansas				
Kentucky	x			x
Louisiana	x[c]		x	x
Maine	x		x	x
Maryland				
Massachusetts	x		x	x
Michigan	x		x	x
Minnesota	x		x	x
Mississippi				
Missouri	x			
Montana	x			
Nebraska	x			
Nevada				
New Hampshire				
New Jersey				
New Mexico	x		x	
New York				
North Carolina				
North Dakota	x		x	x
Ohio	x	x	x	x
Oklahoma	x	x	x	x
Oregon				
Pennsylvania	x		x	x
Rhode Island	x		x	x
South Carolina				
South Dakota	x			x
Tennessee	x	x		
Texas				
Utah	x	x	x	x
Vermont				
Virginia				
Washington				
West Virginia				
Wisconsin				
Wyoming	x			x

[a] By terms such as "embryo," "product of conception," "conceptus," or "unborn child."

[b] Statute could be interpreted as prohibiting some pre-embryo research.

[c] Louisiana statute found unconstitutional in *Margaret S.* v. *Edwards*, 794 F.2d 994 (1986).

SOURCES: Ariz. Rev. Stat. Ann. Sec. 36-2302 (1986); Ark. Stat. Ann. Secs. 82-436, 442 (Supp. 1985); Cal. Health & Safety Sec. 25956 (West 1984); Fla. Stat. Ann. Secs. 390.001(6), 873.05 (1987); Ill. Ann. Stat. ch.38, paras. 81-26, 32 (1987); Ind. Code Ann. Sec. 35-1-58.5-6 (West 1986); Ky. Rev. Stat. Sec. 436.026 (1985); Ky. Rev. Stat. Sec. 311.720 (1983); La. Rev. Stat. Ann. Secs. 14:87, 121-133 (1987); Me. Rev. Stat. Ann. tit.22, Secs. 1593-95 (1980); Mass. Gen. Laws Ann. ch.112, Secs. 12J,K (1983); Mich. Comp. Laws Secs. 333-2685-2692 (1980); Minn. Stat. Ann. Secs. 145-421,422 (Supp. 1986); Mo. Rev. Stat. Secs. 188.015,037 (Vernon 1983); Mont. Code Ann. Sec. 50-20-108 (1987); Neb. Rev. Stat. Sec. 28-346 (1985); N.M. Stat. Ann Secs. 24-9A-1 to 6 (1979); N.D. Cent. Code Sec. 14.02.2-01 (1981); Ohio Rev. Code Ann Sec. 2919.14 (Page 1987); Okla. Stat. Ann. tit. 63, Sec.1-735 (1984); Pa. Stat. Ann tit. 18, Secs. 3203, 3216 (1983); R.I. Gen Laws Sec. 11-54-1 (Supp. 1987); S.D. Cod. Laws Ann. Sec. 34-23A-17 (1986); Tenn. Code Ann. Sec. 39-4-208 (1982); Utah Code Ann. Sec. 76-7-310 (1978); Wis. Stat. Ann Sec. 51.61 (Supp. 1986); Wyo. Stat. Sec. 35-6-115 (1977).

Box 13-A.—Summary of State Laws That Specifically Address In Vitro Fertilization

Kentucky.—Kentucky mentions IVF in its adoption statutes, only to say that nothing in a statute prohibiting adoption in certain instances prohibits IVF.

Illinois.—Illinois' fetal research statute specifically says that it is not intended "to prohibit the performance of in vitro fertilization," when it says that nontherapeutic experimentation on a "fetus produced by the fertilization of a human ovum by a human sperm" is prohibited.

Louisiana.—Louisiana passed a law in 1986 concerning "in vitro fertilized" ova, thereby seemingly excluding embryos created in vivo, whether or not subsequent lavage and transfer were contemplated. The law forbids the purposeful creation of an in vitro embryo solely for the purpose of research or sale. The law also expressly prohibits the sale of a human ovum.

The Louisiana law is novel in that it expressly grants the status of "juridical person" to the fertilized ovum, until such time as it is implanted in a uterus, when presumably its status is governed by State law applying to products of conception in utero. As a juridical person, the fertilized ovum may sue or be sued, and may not be considered property. Instead, the gamete donors are considered its parents, and if they are unidentifiable, the medical facility is considered guardian of the fertilized ovum. The gamete donors may allow another couple to adopt the embryo. Inheritance rights do not attach until birth, and then attach to the birthing or adopting parents, rather than the genetic parents. No person, including the gamete donors, may intentionally destroy an in vitro embryo that appears capable of normal development. IVF facilities are particularly noted as having a direct responsibility for the safekeeping of the embryo. Further, while such facilities and their personnel are protected from strict liability claims by the embryo, they are not so protected from strict liability claims brought by other interested parties.

The law restricts IVF practice to those facilities complying with the personnel qualification and physical plant guidelines of the American Fertility Society or the American College of Obstetricians and Gynecologists.

New Mexico.—New Mexico defines IVF and then states that "clinical research" is to be construed "liberally to embrace research concerning all physiological processes in man and includes research involving human in vitro fertilization, but shall not include human in vitro fertilization performed to treat infertility; provided that this procedure shall include provisions to insure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient, and no physician may stipulate that a woman must abort in the event the pregnancy should produce a deformed or handicapped child" [Sec. 324-9A-1 (D)].

The restrictions on research thus do not apply to IVF conducted to treat infertility, even if they are experimental or unproven in some sense. Thus this law's effect on IVF does not appear to be significant.

Pennsylvania.—Pennsylvania defines IVF as "the purposeful fertilization of a human ovum outside the body of a living human female" (Sec. 3203). It then requires that all persons conducting or experimenting in IVF "file quarterly reports with the department which shall be available for public inspection and copying." The reports must include the names of the persons conducting or experimenting in IVF, the locations, the sponsor of the research, number of eggs fertilized, number destroyed or discarded, and number transferred ("implanted") in a woman. The names of the persons or couple providing the gametes are not required to be reported. Failure to file a report is subject to a fine of $50 a day.

A telephone call to the State official in charge of these records in 1985 revealed that reports are filed by many programs, though no effort to monitor programs to see if they are complying with the law has occurred. Nor is it clear what purpose collection of these data now serves, since they do not appear to have been used for any regulatory purpose or sought by researchers.

SOURCE: Office of Technology Assessment, 1988.

of an attempt to discourage the use of abortion (other aspects of the statute were found to have this purpose), and for that reason was unconstitutional. If this latter reasoning were adopted by other courts, it would increase the possibility that general bans on experimentation with fetal tissue, regardless of source, could survive constitutional scrutiny because they would no longer make the unjustifiable distinction between fetal tissue obtained by abortion and that obtained by miscarriage.

Discretion over discard of embryos does not generally appear to be considered by fetal research statutes. Almost all address what can be done with the product of abortion, but do not address restrictions on abortion itself. Thus, they would not appear to affect the decision to discard an embryo. Even the four States that would arguably prevent research on discarded embryos (see table 13-2) do not address the legality of discard itself.

Discretion over discard of embryos is specifically addressed, however, by Louisiana's IVF law, which states that even the gamete donors may not discard a viable embryo. Instead, they may preserve it for later use or donate it (without compensation) to another couple. Physicians and IVF facilities are directed to take every precaution to preserve the viability of the IVF embryo.

Although some prosecutorial authorities have indicated that they will not prosecute IVF programs under their fetal research laws if all embryos are transferred to a uterus, it is not clear they have a statutory basis for such a position. Further, transfer of grossly abnormal embryos resulting in miscarriage might be a violation of a physician's duty to the patient.

Juridical Status of the Extracorporeal Embryo

There are mixed indications of whether the preimplantation embryo will be treated as the property of the gamete donors. Some commentators have written about viewing sperm and ova as property, and have speculated about the extension of this concept to embryos (42). Judicial decisions have begun to wrestle with the question as well. For example, in a challenge to the Illinois IVF law, a court accepted the notion that an IVF patient is pregnant as of the moment her egg is fertilized, even though the fertilization is extracorporeal (71). The implication is that any decision concerning disposal, particularly destruction, must be made with the woman's consent, as is done for any form of pregnancy termination. In such a case, it is unclear whether this privilege is based on notions of control of property.

On the other hand, a couple successfully sued for $50,000 in damages when their preimplantation embryo was deliberately destroyed after an IVF treatment was canceled by the clinic (24). Nevertheless, the trial-level case set no precedent outside its own district; further, it awarded damages for intentional infliction of emotional distress, rather than for conversion or trespass to chattel, which are causes of action for interference with the property rights of another (59).

The Louisiana IVF law defines the extracorporeal in vitro fertilized ovum as a "juridical person," specifically stating that the gamete donors have parental rather than property rights with respect to the embryo. It further states that the extracorporeal embryo is able to sue and be sued, implying that actions adversely affecting its viability or its health upon birth are subject to legal consequences. In many States, persons have the right to sue for injuries sustained prenatally (10,44,63), but the Louisiana law goes further, granting to the embryo the right to sue for injuries, rather than having these rights accrue upon birth. Granting rights of personhood to an embryo, extracorporeal or in utero, could conflict with the U.S. Supreme Court ruling in *Roe v. Wade*, which stated explicitly that the unborn are not "persons" within the meaning of the 14th Amendment's due process and equal protection clauses (62). However, the Louisiana law has not yet been tested in court.

Later Implantation for Same Couple

The physician or institution providing the in vitro service will be responsible for adequate storage of any frozen embryos being kept for later use by the same couple. Failure to exercise reasonable care could leave the service provider open to liabilities stemming from medical malpractice, negligence, intentional or negligent infliction of mental distress, interference with property, or breach of contract. Such a case could arise, for example, where a malfunctioning incubator damages stored embryos.

Not every embryo loss would leave the provider liable; the technology of embryo freezing and storage is still too undeveloped to offer any guarantee that the embryos will all survive. Yet, failure to operate a storage facility that meets the average standards of practice of the industry certainly would be strong evidence of negligence (53). Furthermore, any deliberate destruction of the embryo, such as took place in the case mentioned in the preceding section, would almost certainly leave the provider liable. The Louisiana IVF law specifically prohibits the physician or institution from destroying the embryo. It absolves the physician and institution from strict liability for screening, fertilization, preservation, and transfer of the ovum, but only with respect to actions brought on behalf of the fertilized ovum. Thus, strict liability might be applicable in a suit by the gamete donors. Further, it absolves the physician and institution from any liability to the embryo if actions were taken in "good faith," but fails to clarify whether a well-intentioned but negligent action would be covered.

"Strict liability" is a legal doctrine generally applied to either ultrahazardous or unnatural activities with a great propensity for harm regardless of how carefully undertaken. Under this doctrine, in order to collect damages a plaintiff need only show that the defendant's actions harmed the plaintiff. It is unnecessary to show that the defendant was negligent. In essence, the doctrine places financial responsibility for harm on those who choose to undertake these activities, regardless of their efforts to be careful or their good intentions. The activities that might qualify for strict liability have been the subject of much discussion, a number of cases, and several efforts by the American Law Institute's codifications of case law, known as "Restatements" of the law. In light of the high rate of early embryo loss in both natural and in vitro fertilization, it is difficult to predict whether IVF would ever become subject in any particular State to strict liability principles.

Calculating the damages from the loss of an embryo would be difficult as this is an unsettled area of law. One calculation could focus on the cost of obtaining a replacement embryo. Another could be the calculation of the net value of the potential child that was lost (35).

Trusts and Estates

Problems regarding trusts and estates are raised by the prospect of frozen embryos left unimplanted after the death of one or more of the genetic parents, as occurred in the Australian case of the Rios embryos (see box 11-A in ch. 11). Controversy developed over whether the embryos should be discarded, given to another couple to gestate and raise as theirs, or given to another to gestate and raise as the orphaned children of the Rioses. Although the embryos were genetically related only to Mrs. Rios, the intended rearing father (her husband) had consented to the use of donor sperm, a fact that would have made him the legal father of the embryos upon birth. This last scenario could conceivably have made the offspring heir to the considerable Rios fortune, and explains in part the international attention that was focused on these frozen embryos (70).

Further, in other areas of trusts and estates law, the validity of certain legacies is determined by whether the beneficiaries will be completely identifiable within a certain period of time. This period of time depends partly on identifying those "lives in being" at the time the legacy is created (16). Although clearly frozen extracorporeal sperm are not lives in being, the same cannot be stated as categorically for a frozen embryo, although constitutional decisions holding that the unborn are not "persons" under the 14th Amendment may prevent States from defining frozen embryos as "lives in being" (62).

The Louisiana IVF law grants inheritance rights to the embryo at the time of birth. Further, the resulting child would inherit from the woman who gives birth (and her husband, if any), rather than from the gamete donors. The provision is unclear, however, with respect to a number of problems. For example, if the woman giving birth were unmarried, it is unclear whether the child could inherit from the genetic father if his sperm were used as that of an anonymous sperm donor rather than an intended rearing parent. Further, if the genetic father is deceased but his wife, the genetic mother, gives birth many years later by bringing to term a previously frozen embryo, it would appear necessary to reopen probate of the father's will in order to account for this new child. With no time limit specified for inheritance purposes, such events pose real problems for the orderly disposition of estates. The ambiguities in the Louisiana effort to account for inheritance rights of extracorporeal embryos simply point out some of the many complexities of trusts and estates law in this area, a topic beyond the scope of this report.

GAMETE INTRAFALLOPIAN TRANSFER

Gamete intrafallopian transfer involves transfer of ova and sperm by catheter to the fallopian tubes, where fertilization may take place (see chs. 7 and 15). As both donor sperm and donor eggs can be used, GIFT can raise all the same questions of relative rights and responsibilities among gamete donors and gestators as are raised by IVF. In one sense, GIFT simplifies the legal issues raised by noncoital reproductive technologies, because it eliminates the presence of the extracorporeal embryo. This avoids the difficulties posed when embryos are left frozen after the death of the genetic parents, and also avoids the possibility of commercial cryobanking of embryos.

EMBRYO TRANSFER

This section considers the situation in which a child will be raised by a gestational mother and her husband or partner, using an embryo that was donated. Embryos may be donated in one of two ways. First, embryos may be donated by couples who have embryos left over from an IVF procedure. In this situation, the gestational mother will rear a child to whom neither she nor her husband are genetically related. The genetic parents of the embryo are referred to as embryo donors. Although this can occur with fresh embryos, problems of synchronizing the recipient's cycle make it more likely to occur as cryopreservation of embryos becomes more common.

Second, a woman may deliberately undertake to donate an ovum to another. For example, she may undergo laparoscopy or sonography-guided egg retrieval so that the recovered eggs can be fertilized in vitro before being implanted in another woman's womb. In this situation, the gestational mother's husband usually donates the sperm to be used for the fertilization, and the term ovum donor is used to refer to the woman undergoing egg retrieval.

A variation on this method for donation is for the ovum donor to become pregnant by artificial insemination with the intended gestational mother's husband's sperm, in order to have the fertilized egg washed from her uterus by lavage and then donated to the gestational mother. Since the lavage removes an embryo from the uterus before it has implanted, it probably cannot be considered an abortion; use of an intrauterine device may also induce the removal of a fertilized ovum before implantation, but is not viewed under the law as equivalent to an induced abortion. Nevertheless, the precise classification of artificial insemination followed by uterine lavage remains somewhat ambiguous. Embryo donation by artificial insemination and lavage, or by egg retrieval and IVF with the intended rearing father's sperm, is quite rare and may remain uncommon (see ch. 15).

The situation in which an embryo is carried to full term by a gestational mother and then returned to the gamete donors for rearing—gestational surrogate motherhood—is considered in chapter 14.

Existing Legislative Controls

With the exception of Louisiana and Kentucky, no State has statutes specifically addressing embryo donations of any type. The tendency or practice of some persons to speak of embryo donations as "embryo adoptions" can be misleading legally, since State adoption laws have always involved transfer of rearing rights and duties in a live-born infant rather than in an unimplanted embryo.

Fetal research statutes generally cannot be read to prevent the donation of embryos created in vitro or by artificial insemination followed by lavage. In five States,[3] however, prohibitions on donating fetuses for research or experimentation might be interpreted to include embryo donation for gestation, if the definition of fetus were extended to include embryos and the transfer process were viewed as experimental. In Nebraska and Wyoming, this same conclusion might be drawn if, in addition, the embryo resulted from an abortion, arguably true in the case of artificial insemination followed by lavage for the purpose of fertilized ovum donation (4).

By contrast, the Louisiana IVF law (which applies only to ova fertilized in vitro rather than by artificial insemination) specifically preserves the possibility of donating the embryo, but does not permit any compensation for the donation. It allows gamete donors to renounce their parental rights, at which time the embryo can be donated to another. The drafting of the statute makes it unclear, however, whether only married couples may accept the donated embryo. It is also unclear from the drafting whether the IVF facility can limit donations to persons meeting criteria it specifies.

Kentucky Revised Statutes Section 199.590, which prohibits payment in connection with adoption, was revised in 1984 to read:

> Nothing in this section shall be construed to prohibit in vitro fertilization. For the purposes of this section, in vitro fertilization means the process whereby an egg is removed from a woman, then fertilized in a receptacle by the sperm of the husband of the woman in whose womb the fertilized egg will thereafter be implanted.

Subsequent court dictum in the 1986 Kentucky case *Surrogate Parenting Association* interpreted the section to mean that embryo donation is permitted when the gestational mother and genetic father are married to one another and intend to raise the child themselves (74). ("Dictum" is commentary that is not strictly necessary to the decision on the case before the court; it is used by judges to explain their reasoning and to draw analogies to other fact situations. Although dictum has no precedential value, it can be persuasive to other courts, and can provide a clue as to future judicial decisions in related areas of law.) However, no case has arisen in Kentucky to test this interpretation or to determine legal maternity in the event of a dispute between a genetic and a gestational mother.

The Kentucky statute addresses embryo transfer involving an ovum donor who undergoes egg retrieval so that the ova may be fertilized with the gestational mother's husband's sperm, but it does not address the question of the more common form of embryo donation, which involves the transfer of "surplus" embryos from one couple to another. By its terms, the Kentucky statute cannot apply to this situation, as the gestational mother's husband would not be the genetic father of the resulting child. However, there is nothing in existing Kentucky law that prohibits such transfers either.

No other State statutes address embryo transfer. Nor can the State artificial insemination by donor laws be easily interpreted to extend to male and female gametes alike, since they use the term "sperm" or "semen." It is likely that courts would give legal effect to the agreement between the parties to an embryo donation if it paralleled sperm donation—i.e., if an ovum donor has no rearing rights and duties and the consenting embryo recipient (who will also gestate) and her partner (who will be the genetic father) assume them. Yet, embryo donation entails greater risk to the ovum donor than does sperm donation.

The risks of ovum donation depend on a number of factors, including the method by which the ova are recovered. Laparoscopy involves the risks of abdominal surgery, such as infection and anesthesia. Sonography-guided vaginal retrieval also poses a risk of infection, and both egg recovery techniques may be used in conjunction with drugs to stimulate ovulation, thus posing the risk of side effects. Artificial insemination followed by uterine lavage and embryo retrieval risks unintended or ectopic pregnancy, as well as the transmission of infectious disease by the semen used for the insemination.

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[3] Maine, Massachusetts, Michigan, North Dakota, Rhode Island.

These risks may strongly influence the development of paid ovum donation, as professional societies such as the American Association of Tissue Banks recommend that their members not accept tissues if it entails "undue risk" to the donor. The difference in risk associated with these forms of embryo donation as opposed to sperm donation might be used by professional societies and lawmakers to justify regulation or prohibition of paid embryo donation, at least when it is undertaken solely to earn money and not in conjunction with a therapeutic or diagnostic procedure needed by the ovum donor herself.

Some restrictions on commercial embryo donations do exist. Payment for a human embryo is specifically banned in Louisiana and Florida, and some of the State fetal research statutes prohibit the sale or transfer of embryos for experimental purposes. Eleven States that prohibit selling fetuses for experimentation use language potentially broad enough to affect the sale of embryos conceived in vivo (10,11,12).

Professional Responsibility

Professionals who facilitate embryo transfer have responsibilities with regard to ensuring that there is informed consent by all parties to the procedure, that the sperm and ova are properly screened, and that the resulting embryo is preserved as well as current technology permits.

Ensuring informed consent is difficult when the risks of a procedure are still poorly understood. Under these circumstances, physicians are generally required to err on the side of caution and to present even those risks that seem quite remote (34). Relatively unexplored procedures, such as artificial insemination followed by lavage, pose just this dilemma.

There are no State laws on recordkeeping and confidentiality with respect to embryo donation. As these donations require a medical procedure, however, hospital or at least office records are likely to exist for each donor. Such records are ordinarily held in confidence, but are subject to disclosure upon court order or at the request of the patient herself (39).

No legal constraints on techniques for ovum screening exist, although professional guidelines have been issued by the American Fertility Society, in addition to those issued with regard to sperm donation. Further, there are no statutory requirements that physicians screen fertilized ova for morphological indications that they are not viable, but it is nevertheless a common practice at IVF clinics. Even so, some clinics transfer embryos that may have little chance of implanting and coming to term, both because the dearth of embryo research has made it difficult to predict with certainty which embryos will implant successfully and because of a desire to avoid the ethical issues raised by the deliberate discard of fertilized eggs (84).

Responsibility for storage of a cryopreserved embryo will always fall on the institution providing the service. But the party to whom the institution is liable in the event of negligence may change, depending on who is considered the "owner" of the frozen embryo and who intends to raise the resulting child. If an embryo has been donated to another couple, and this donation is evidenced by some sort of written or oral agreement, the intended recipients might be viewed as the "owners," at least with respect to control over decisions concerning disposition of the embryo. This scenario has not yet been tested in any court of law.

Embryo Donor's Rights and Duties to Child

Using the analogy of the sperm donor's rights and duties to his genetic offspring, a couple donating an embryo to another would presumably have no rights or duties to the child. As only the donors are familiar with their own genetic backgrounds, however, they might have a duty to warn the recipient of potential genetic problems in the offspring. If the resulting child is in fact born with a genetic problem that could have been identified if the donors had warned the recipient of its possibility, there might be two causes of action. First, the recipient might sue to recover the extra costs of raising a child with these problems. Second, the child might sue the donors. If the problem would have been correctable, then the suit would be for the pain and suffering of living with the disease. If the problem were unavoidable except by abortion, the child might sue for "wrongful life," alleging that nonexistence would have been preferable to diseased existence.

Such wrongful life suits have met with limited success in U.S. courts, but as the number of identifiable genetic disorders increases, they might become more common (19,21,56,63). Usually they are directed at the physician or genetic counselor who failed to properly advise the parents of the condition. In this situation, both the parents and the gamete donors have a role in identifying the disorder, and thus may be liable to the potential child. A suit against the gamete donors is somewhat analogous to a suit against the genetic counselor, as in both cases a duty exists to disclose information that is uniquely held by that person.

When these suits are directed at the child's rearing parents, it appears at first to be a futile attempt to move funds from the parents' pockets to the child's. In fact, however, the purpose may simply be to obtain funds from the parents' insurer. To date, courts and legislatures have not shown a willingness to countenance such suits against a child's parents (30,67,68). Should this reaction change, however, insurance coverage for such liabilities may be an important factor in the growth of these particular lawsuits. Another key factor would be the development of recordkeeping practices that allow identification of the embryo donors; if they are kept anonymous, then the child and the child's rearing parents would be unable to bring suit. Such anonymity has been a factor in restricting analogous suits against sperm donors.

Requirements for Consent of Ovum Donor's Husband

A husband may have an interest in his wife's decision to be artificially inseminated for subsequent lavage and recovery. There is, however, no common law or statutory duty for a physician to obtain the consent of an ovum donor's husband. Using the analogy of sperm donation, if the ovum donor has no legal rights or responsibilities to the child, it is unlikely that a consent requirement will be developed. There is a key distinction, however, between being an ovum donor and being a sperm donor that might affect consent requirements: the former may inadvertently become pregnant. If she does, and if she chooses to sustain the pregnancy, then her husband could become legally responsible for the child.

Embryo Recipient's Rights and Duties to Child

As the embryo recipient is the intended rearing parent, her responsibilities will probably be identical to those of any mother. Her rights, however, are less clear. As a "gestational mother," she is not clearly recognized in law as the sole woman with claim to be recognized as the "legal" mother. Analogies to date have been limited to questions surrounding fatherhood, in which genetic relationship is generally determinative of parentage (37).

One major exception, however, is the presumption of paternity, which is designed both to protect the needs of the child to have two parents and to preserve the institution of marriage. Similar policies might come to be used to justify a State policy favoring a gestational mother or an intended rearing parent's primacy in any conflict with the genetic mother over custody to the child. In the only two court cases to date, however, prebirth uncontested petitions to have the genetic mothers (rather than gestational mothers) recognized as the legal mothers of the children were granted, subject to postbirth confirmation (72,73). The cases, however, were from lower courts, and so have limited precedential value even within the States in which the courts were sitting. A ruling on a similar case in Virginia is expected in early 1988 (27).

It should be noted, too, that embryo donation will be made by a woman who has undergone an IVF procedure and who has had several embryos left over after the procedure. In other words, the embryo results from an invasive surgical laparoscopy done on a woman who herself was having trouble conceiving. If such a woman subsequently finds that she is unable to have a child, perhaps because she is unable to carry to term, there may be an emotional demand for custody of any child that resulted from one of the embryos, regardless of the gestational mother's own attachment after pregnancy. There is no tested law at all on this subject, and as yet no established principles to predict the outcome in the event of such a controversy.

With regard to the embryo recipient's husband, no statutory requirement for his consent exists when a woman seeks an embryo transfer from an ovum donor, despite the analogy to artificial insemination. Physicians can be expected to individually require such consent if they know that the woman is married, just as many have in the context of artificial insemination. Absent legal constraints, however, such consent is not required. Nevertheless, the presumption of paternity will probably render the husband the legal father of the child, even if his sperm were not used to inseminate the ovum donor nor his consent obtained.

RESTRICTING OR REGULATING THE SALE OF GAMETES OR EMBRYOS

Most States do not prohibit the sale of blood, plasma, semen, or other replenishing tissues if taken in nonvital amounts (55,79), although the prohibitions on organ sales in three States are conceivably broad enough to cover semen sales as well (12). Florida, however, outlaws the sale of human embryos: "No person shall knowingly advertise or offer to purchase or sell, or purchase, sell or otherwise transfer, any human embryo for valuable consideration" [Fla. Stat. Ann. Sec. 873.05(1)]. Similarly, Louisiana's IVF law prohibits paid transfers of fertilized ova.

State laws usually characterize these paid transfers as provision of services rather than sale of commodities, either in the State's version of the Uniform Anatomical Gift Act or in their version of the Uniform Commercial Code (UCC), which governs various commercial transactions, including contracts for the sale of goods. The primary reason for this characterization is to avoid liability for defective products under either general product liability principles or the UCC's implied warranty provisions (18,22,36). In addition, services are not subject to the UCC's specific performance provisions.

Product liability is the name given to the area of law involving the liability of suppliers of goods or products for the use of others, and their responsibility for various kinds of losses resulting from defects in those products. Four possible theories of recovery are available under product liability law:

- strict liability in contract for breach of an express or implied warranty,
- strict liability in tort largely for physical harm to persons and tangible things,
- negligence liability in contract for breach of an express or implied warranty that the product was designed and constructed in a workmanlike manner, and
- negligence liability in tort largely for physical harm to persons and tangible things (59).

Generally, negligence liability may exist with respect to both products and services, but strict liability is applicable only to products. Thus, characterization of blood and semen sales as services enables blood and semen banks to avoid liability if a specimen is contaminated or infected, provided that the bank was not negligent (46).

If sales of gametes and embryos were to be treated as those of goods as opposed to services, then UCC warranties would apply. The UCC provides that commodity contracts (but not service ones) are subject to:

- the implied warranty of merchantability, which requires goods to be of "fair average quality" within the description provided by the seller and fit for the ordinary purposes for which such goods are used (UCC Sec. 2-314), and

- the implied warranty of fitness, which requires goods to be suitable for the buyer's particular purpose to the extent this purpose is known by the seller (UCC Sec. 2-315).

The merchantability warranty only applies to sales by "merchants," defined by the UCC as those who regularly supply the product (e.g., hospitals, tissue banks), but not by occasional sellers [UCC Sec. 2-104(1)]. The fitness warranty applies equally to regular dealers and occasional sellers (UCC Sec. 2-315).

If these transactions were treated as sales of commodities, these implied warranties could result in substantial liability for injuries resulting from transfusion or insemination with a specimen capable of transmitting hepatitis, AIDS, or another contagious disease. Insemination with sperm containing a genetic defect could also result in substantial liability. Since the suit would be based on strict liability for breach of warranty rather than negligence principles, careful examination of specimens for contamination or a genetic flaw would not entitle the providing entity to avoid liability if an injury occurred.

If exchanges involving human gametes and embryos are treated like those involving blood—i.e., if such exchanges are considered to be transactions for services rather than commodities—then certain types of liability may similarly be avoided by tissue and cell banks, research institutions, hospitals, and companies. Although liability would continue to exist for negligence (e.g., failing to use an available and appropriate test to screen suppliers for viral infections), there would be no liability for imperfect specimens in the absence of negligence. Avoiding the concept of an imperfect specimen with respect to embryos might also help avoid some of the ethical questions raised by treating embryos as traditional articles of commerce.

The Federal Government has the authority to enter this area to regulate gamete and embryo sales by virtue of the interstate commerce clause (see ch. 9). The ultimate regulation of interstate commerce might be to ban the sale of an article altogether. Of course, the Food and Drug Administration does this implicitly for all drugs and medical devices that have not been proven safe and effective. But Congress has also indicated its willingness to ban the purchase and sale of human body parts, and could certainly ban the interstate sale of human embryos, as well as sperm and ova. In 1984, for example, Congress passed the National Organ Transplant Act. Although most of the act is aimed at promoting organ transplantation in the United States, Title III is directed exclusively toward prohibiting organ purchases:

> It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. For the purposes of this act, "human organ" is defined to mean "the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin. . . ." Violation carries a five year maximum prison sentence, and a $50,000 fine [Public Law 98-507 (1984)].

Thus, the statute bans the profitable sale of organs, although not the recompense of expenses incurred by the donor. The statute's organ sale prohibition was based primarily on congressional concern that permitting the sale of human organs might undermine the Nation's system of voluntary organ donation (77). It was also driven by concern that the poor would sell their organs to the rich, to the detriment both of poor people who might feel economically coerced to become organ suppliers and those who need but cannot afford transplantable organs. It may also reflect congressional distaste for sales of human body parts generally.

These considerations may or may not apply to the sale of gametes and embryos (29). Semen sales, in particular, involve no physical risk to the donor and have long been tolerated in the United States. Ova sales involve risk to the donor, as she may well be prescribed drugs to induce superovulation, undergo laparoscopy for retrieval of the eggs, or be impregnated by artificial insemination and risk ectopic pregnancy from the lavage technique used to recover the fertilized ovum. Embryo sales may involve the risks of ovum donation, and also raise ethical considerations not present in the sale of gametes (see ch. 11).

MODELS OF STATE POLICY

The approaches taken by State legislatures to the oversight or regulation of noncoital reproduction may be broadly grouped into five categories: static, private ordering, inducement, regulatory, and punitive (25,82). These models are of interest both because they reflect the variation in proposed State legislation and because they serve as an informative guide to Congress, should it choose to consider legislation in this field. Further, constitutional challenges to these State laws could illuminate the boundaries of the right to procreate.

The static approach, one of State legislative inaction, leaves the resolution of familial relationships to case-by-case consideration by the courts. For example, in the District of Columbia and the 20 States without legislation on the topic of artificial insemination, challenges to the legitimacy or legal status of the resulting child could be brought, and judicial determinations would be made based on the effect of any general State legislative presumptions of paternity, the best interests of the child, the understanding of the parties to the insemination, the existence (if any) of an underlying contractual agreement, and other pertinent facts. This nonlegislative approach can be indicative of a lack of consensus among State legislators, or a temporary absence of legislative leadership while courts are given an opportunity to consider several test cases. Alternatively, it could be an expression of hostility to an activity altogether. By failing to provide legislative guides to resolving possible disputes, the legislature can effectively decrease the frequency of the activity within the State by making it a more legally risky venture for the participants.

Private ordering approaches allow the State to validate private arrangements by recognizing underlying agreements or contracts to allocate familial roles to those who participate in artificial insemination by donor or the transfer of embryos for IVF. Artificial insemination statutes that identify the recipient's husband as the legal father of her child only if he consented to the insemination follow this model. Others allow participants to specify that a sperm donor may have a continuing parental role for the child. Legitimizing these choices by State statute and enforcing them by judicial action places the State in the role of facilitating individual choices of all sorts.

By contrast, inducement approaches only validate the parties' underlying intentions or agreements if their actions meet certain legislative conditions. For example, many of the State artificial insemination statutes contemplate only those inseminations done by a physician. The physician requirement can be premised on a number of policies, such as ensuring the physical and genetic health of both sperm donor and recipient, maintaining artificial insemination as a form of medical practice despite the ability of laypersons to perform the procedure, encouraging the use of anonymous donation only, or facilitating the role of physician as a gatekeeper who screens out socially unacceptable recipients and donors. Such a law can encourage conformity to State-sanctioned procedures by denying nonconforming artificial insemination participants the advantage of certain legitimation of the resulting child under State paternity law, or by denying a recipient the advantage of knowing that the sperm donor is unable to reenter her life with a request to be acknowledged as the father of her child. The case of *Jhordan C.* (43) in California exemplifies the results of the inducement approach, as the lack of physician-supervised insemination allowed the court to fashion a unique distribution of parental rights and responsibilities that precisely followed neither the parties' original intentions nor those set forth under the California artificial insemination by donor statute.

A prominent example of a regulatory approach is the Louisiana IVF law, which specifies that IVF be done in accordance with the standards of practice suggested by prominent medical professional societies. This translates into legalization of clinics staffed and equipped to the levels identified as desirable by groups such as the American Fertility Society or American College of Obstetricians and Gynecologists, and implicitly makes illegal those clinics that fail to meet these guidelines. Further, the Louisiana law attempts to specify a variety of rights held by an embryo in vitro and responsibilities or limits on discretion for the physicians and gamete donors involved. The permissible limits of such State regulation may be subject to constitutional challenge, as would any State effort to take a punitive approach by outlawing a technique entirely. The Louisiana and Florida bans on the sale of embryos exemplify this approach. These bans have not yet been challenged, and so an explicit determination of their constitutionality has not yet been made.

SUMMARY AND CONCLUSIONS

The use of noncoital reproductive technologies raises questions concerning the relative rights and responsibilities of gamete donors and rearing parents. In many cases, these questions are so new that there is little or no guidance as to how the law will be applied. Legal literature and analogies drawn from other areas of law are available in the meantime, to guide participants and courts in their analyses of the rights and duties created by these techniques.

With several configurations of parents available, it is probably not practical to draw an inflexible rule generically stating that all gamete donors are the legal parents of their progeny, or that all intended rearing parents have sole rights and responsibilities to their children. Case-by-case consideration of the parties' intentions, however, would probably yield a collection of rules. To date, the courts have not been presented with the full range of these situations, and thus have been restrained by the Constitution from making pronouncements on all possible parental configurations.

Legislation, which is prospective rather than retrospective in nature, could be drafted to clarify these relationships and to safeguard the interests of the children born as a result. Legislation, too, could fill in the gaps concerning the status of children born to single women using artificial insemination, the control over the disposition of extracorporeal embryos, and the maintenance of records documenting the genetic parentage of children born by these techniques.

Absent legislative directives, courts will continue to decide cases that come before them, and to develop rules that help make the legal implications of these parental relationships more predictable. But as the courts in the District of Columbia and each of the 50 States are free to come to their own conclusions concerning these rules, there may long be significant State-to-State variations in the law.

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Chapter 14

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Chapter 14

Legal Considerations: Surrogate Motherhood

Surrogate motherhood is more a reproductive arrangement than a reproductive technology. It may require neither physician nor complicated equipment. It does require more complicated personal arrangements than are usual for bringing a baby into the world. Most often, it is used by a married couple in which the wife is either unable to conceive or unable to carry a pregnancy to term. It has also been used by at least one single man wishing to form a family.

By the beginning of 1988, almost 600 babies had been born through surrogate motherhood arrangements. For many who use the arrangement, it is an alternative to adoption, which can take years to complete and may be unavailable to those not meeting traditional criteria for an adopting home. For others, it is the only way to have a child genetically related to the rearing father. For these people, adoption is not an acceptable alternative.

Most commonly, "surrogate mothers" are women who are impregnated by artificial insemination with the sperm of a man who intends to raise the baby. He is generally married, with an infertile wife. Of course, donor sperm could be used if the man were also infertile. This, however, may change the legal consequences of the contract arrangements, as the intended rearing father would not have the legal status generally enjoyed by biological fathers.

Surrogacy can also be used with embryo transfer. In this case, a "surrogate gestational mother" is impregnated with an embryo created in vitro. Usually the embryo is formed with the sperm and egg of the intended rearing parents, but donor sperm and egg can be used instead. Once again, the use of donated gametes may have legal consequences.

Commercial surrogacy arrangements generally provide that a woman will be paid for the time and effort it takes to conceive and carry the pregnancy to term, with the bulk of the payment coming at the time she relinquishes the child and her parental rights to the intended rearing father. Surrogate motherhood is viewed by some as unacceptable, as a form of baby-selling; others see it a viable alternative for couples who would otherwise wait years for an adoptable baby and for those who want a child genetically related to the rearing father.

Despite a considerable amount of earlier publicity, it was the controversy over Baby M (see box 14-A) that thrust surrogate motherhood squarely into the national consciousness. Although the case

Newsweek
Mothers for Hire
The Battle for Baby M

Media coverage of *Baby M* Case.

SOURCE: *Newsweek*.

exemplified some of the difficulties associated with this particular reproductive arrangement, most surrogate matching services reported to OTA that inquiries increased after surrogate mother Mary Beth Whitehead refused to give up her parental rights in favor of those of Elizabeth Stern, wife of the baby's genetic father, even inquiries to the agency directly involved in the *Baby M* case (38). At the same time, more custody suits have been initiated by women wishing to retain custody of the children they bore pursuant to surrogate contracts (54,69).

Box 14-A.—The Case of *Baby M*

William and Elizabeth Stern were a couple with no children. Mary Beth Whitehead responded to an advertisement by the Infertility Center of New York, was quickly approved, and became pregnant by artificial insemination with William Stern's semen. She was to earn $10,000 on the day she delivered a baby to the Sterns. If she miscarried, she would have earned a nominal fee.

Immediately after the birth of the baby girl, Mrs. Whitehead became distraught at the thought of giving her up. She convinced the Sterns to let her have the baby for a few days, and then fled to Florida, where she remained despite a court order directing her to deliver the baby into the custody of Mr. Stern. The baby lived with Mrs. Whitehead for 4 months, until Mr. Stern regained temporary custody of the child. Baby M then lived with the Sterns for 8 months while a trial went on in Hackensack, NJ, to determine whether the surrogacy contract signed by the Whiteheads and the Sterns was enforceable.

On March 31, 1987, the judge issued a 120-page ruling in which he awarded permanent custody to Mr. Stern (30). Further, he permanently canceled Mrs. Whitehead's visitation privileges, terminated her parental rights, and processed Mrs. Stern's petition for adoption. The court based its ruling both on the enforceability of the underlying surrogacy contract, and upon a finding that it was in the best interests of the child to live with the Sterns.

On February 3, 1988, the New Jersey Supreme Court reversed the trial court, finding that the surrogacy contract violated New Jersey law concerning baby-selling, adoption, and termination of parental rights (30). The court voided Mrs. Stern's adoption proceeding, and reinstated Mrs. Whitehead's status as legal mother of the child, but upheld the trial court's order (based on the best interests of the child) to award custody to the Sterns, with visitation provisions to be worked out by the families and the trial courts.

SOURCE: Office of Technology Assessment, 1988.

Although there have been a number of lawsuits concerning custody or challenging adoption laws that appear to prohibit payments to surrogates, the majority of surrogacy arrangements proceed without judicial involvement, with few reported instances of parties reneging on their agreements. Preliminary psychological and demographic studies and as well as surrogate matching service reports to OTA demonstrate that women who have volunteered to be surrogates are distinctly less well educated and less well off than those who hire them, but their self-reported motivations for offering to be surrogates include noncommercial considerations (26,43,51,52,57,65). It should be noted, however, that absent financial remuneration, few say that they would offer to participate as surrogates (51,52).

This chapter reviews the legal issues raised by surrogate motherhood, and summarizes the legislative approaches proposed to date. It also reports on the findings of OTA's survey of surrogate matching services in the United States (see box 14-B). The chapter focuses largely on the situation in which a woman agrees to be artificially inseminated and to relinquish the child at birth to the genetic father. Instances have already arisen, however, in which women have been asked to carry to term fetuses to whom they are genetically unrelated, by implantation of an embryo conceived by artificial insemination followed by lavage, or by in vitro fertilization (IVF). The parental configurations arising from such arrangements can be quite complicated. For example, a 48-year-old grandmother in South Africa carried to term three embryos created in vitro with the eggs of her daughter and the sperm of her son-in-law (7). The special legal issues associated with this type of surrogacy are considered separately near the end of this chapter. Embryo donation to a gestational mother who intends to raise the child she bears is discussed in chapter 13.

Box 14-B—The OTA 1987 Survey of Surrogate Mother Matching Services

As part of this assessment, OTA surveyed surrogate mothering matching services around the country. Names and addresses were obtained from one 1985 publication (3), from Associated Press wire service reports, and from word-of-mouth. Of 27 services contacted, 5 were no longer in business, 5 had moved with no forwarding address, 4 failed to respond, and 13 returned completed questionnaires.

The questionnaire asked for information on agency demographics (time in operation, personnel, extent and nature of matching services); physical, medical, psychological, and social criteria for screening clients and surrogates; typical contract terms, including fees; demographics of the client and surrogate populations (age, race, religion, economic and educational attainments, marital status, and sexual orientation); and opinions held by the directors on the subject of potential State and Federal regulation of surrogate motherhood. Each service was contacted at least three times by mail and once by telephone in an effort to obtain a response.

Because it is difficult to identify all the services, physicians, and lawyers who occasionally make a match, the results of the survey are not presented as projections to the entire population of surrogates, clients, or matching services. Further, one of the nonrespondents reputedly has the largest practice in the United States, although his own publications and interviews (37,39) reflect a practice that is substantially identical to most of those responding in this survey.

SOURCE: Office of Technology Assessment, 1988.

FINDING AND CHOOSING A SURROGATE MOTHER

Who Hires A Surrogate Mother?

Surrogate mothers can be sought privately by asking friends or by placing an advertisement in a newspaper. In addition, a number of organizations have sprung up that attempt to provide surrogate matching services. These groups reported to OTA that the overwhelming majority of their clients are in their late thirties or early forties. While all services reported that at least 90 percent of their clients are married couples, there are five reports of unmarried couples and nine reports of single men who were accepted by an agency to hire a surrogate mother. The number of homosexual individuals or couples who seek to hire a surrogate mother is consistently reported as no more than 1 percent, but three agencies have sought surrogates for a homosexual male couple, and one for a homosexual female couple. Several agencies also stated that they would provide service to singles or homosexual couples should they be asked. One agency found a surrogate mother for a single man who also sought to select sperm (see ch. 15) to increase the chances of having a boy (39).

Clients are drawn from a wide range of religious affiliations, with approximately 25 percent Catholic, a similar proportion Jewish, and approximately 42 percent Protestant. More than 95 percent are reported as white couples, and on average the agencies reported that about 25 percent of the couples are already raising a child.

Agencies uniformly reported that clients must be in good health and economic circumstances to hire a surrogate; two-thirds offer or suggest psychological counseling but do not require home review. The sperm donors are required by at least half the agencies to undergo a physical examination and two-thirds require testing for sexually transmitted diseases. This latter practice may change in the future if there is continued Federal interest in the risks associated with artificial insemination (see ch. 9).

Those seeking to hire a surrogate mother are generally well off and well educated. Overall, agencies reported that approximately 64 percent of their clients have a household income over $50,000, with an additional 28 percent earning $30,000 to $50,000 per year. One-third of the services reported that at least half of their clients have been to graduate school, and another third reported that at least 80 percent of their clients have been to graduate school. Overall, the services reported that at least 37 percent of their clients are college-educated, and another 54 percent have attended graduate school.

Commercial Surrogate Matching Services

Some surrogate matching services are staffed by multidisciplinary teams of medical doctors, psychiatrists, lawyers, and administrators; others are primarily law firms with connections to other professionals should their clients wish a referral. Most services surveyed by OTA had been in business more than 3 years, but a number of those listed in a 1985 publication (3) were no longer active by 1987. With one exception, their volume of business was quite small, but as of late 1987 these agencies were making at least 100 matches a year, and over time their matches had been responsible for the births of almost 600 babies.

Brokers who enter the business of recruiting and matching surrogates to intended parents are in a novel industry. Nevertheless, in general, any commercial service is held to a standard of careful practice at least akin to general industrywide practice. Commercial brokers may well be held to "expert," high standards of care, and may share responsibility with physicians and attorneys for failing to adequately inform, screen, and counsel participants. Brokers who are themselves physicians or lawyers will also be subject to ethical and regulatory standards of conduct set by their respective professions and by State law.

Photo credit: Library of Congress

Surrogate mother matching service.

At least four centers have been involved in lawsuits arising from arrangements that went awry—e.g., for failure to provide adequate medical information, failure to have a signed contract prior to insemination, approval despite a history of heart disease, and use of fertility drugs to induce ovulation in a woman who was still nursing her son (24). Another lawsuit concerned a baby born with severe health problems and unwanted by either the sperm donor or the surrogate mother he had hired. In a Washington State case, an already pregnant woman was screened and accepted for a surrogate program, leading to charges of theft and fraud when she failed to give back the money she'd been paid (8). The outcome of such lawsuits will help clarify the standard of practice that will be demanded of surrogate matching services.

Screening of surrogates varies somewhat among the matching services. All require that the surrogate be in good health (verified by a physical examination), and all but one require that the surrogate be in a stable relationship and have had a prior conception. Half require that she be economically self-supporting, often explicitly excluding those on welfare. Agencies generally accept only women between the ages of 21 and 35 to be surrogates, but at least two accept women at age 20, and at least one at age 18. Over half require some sort of psychological screening or counseling, but the extent of that counseling is not clear from the OTA survey results.

Commercial brokers may also find that they are subject to existing State licensing laws. Several States require that persons or agencies arranging adoptions be licensed. Such a requirement could apply to the intermediaries who recruit surrogates for interested parties, who negotiate and write the contracts, and who then handle the post-birth adoption proceedings. In these States, refusal to license such brokers could have a substantial impact on the availability of surrogate services.

Two States appear to require such licensing, at least in order to charge a fee for the matching service. In an unchallenged advisory opinion, the Ohio attorney general stated:

> The Department of Welfare may reasonably conclude that a person or organization not licensed by the Department as a child placing agency . . . is prohibited . . . from engaging in any of the following activities: (1) the solicitation of women to become artificially inseminated . . . for the purpose of the women bearing children and surrendering possession of the children and all parental rights to such men and their spouses (49).

The attorney general of Louisiana stated that "[only] if the go-between is a nonprofit agency properly licensed [is] there . . . no jeopardy in accepting [the state] authorized [adoption] fees" (44). These fees are set by the State, and Louisiana adoption law prohibits any further payments, except for the actual medical and associated expenses of the mother during her pregnancy.

On the other hand, at least one State has explicitly recognized the right of a nonlicensed corporation to act as a surrogate matching service. The Supreme Court of Kentucky has held that preconception agreements to relinquish a child for money do not violate Kentucky law, and therefore declined the Kentucky attorney general's request to revoke the charter of Surrogate Parenting Associates, a matching service in Louisville. (64). Similarly, a New York court held that an attorney who facilitated an adoption proceeding pursuant to a surrogate motherhood arrangement was entitled to receive $3,500 for his services (29).

If commercial brokers are subject to adoption agency licensing, licensure may also determine whether an agency can advertise for clients. For example, Alabama, Georgia, Nevada, New York, North Carolina, and Oklahoma permit only licensed "child-placing agencies" to advertise. Only Kansas has addressed this question with respect to surrogacy: In 1984, its State adoption code was amended so that restrictions on advertising did not apply to surrogacy arrangements. However, no accompanying legislation addressed the legality of paid surrogacy or the enforceability of surrogacy contracts (Kansas Statutes Annotated Sec. 65-509) (50).

At this time no explicit restrictions have been placed on the techniques used by matching services to seek surrogate mothers, and OTA identified at least 10 centers that do use advertising or direct mail solicitation to find potential surrogates. One service has run advertisements in a student newspaper whose readership is largely between the ages of 16 and 23 (10). Advertisements suggesting that girls under the age of 21 might deliberately become pregnant in order to earn a fee may be a cause for concern.

Physicians

Physicians are often involved in surrogacy arrangements when they are called upon to screen surrogates or intended rearing parents for their physical and mental health. They are also usually responsible for performing the artificial insemination. To the extent that they are participants in a surrogate matching service, they may incur obligations to their partners and clients beyond those normally associated with a patient-physician relationship.

Physicians have a professional responsibility to examine patients thoroughly and to explain the consequences of any medical procedure. Such a requirement falls within the guidelines of professional societies, State laws, and medical malpractice case law (see ch. 9). For surrogate mothers, this would include information on the risks of insemination, pregnancy, and childbirth. It might also include a duty to screen the genetic father for infectious diseases that might be transmitted by his semen during artificial insemination. To the extent that physicians work within a brokering agency, they may also owe a duty to the in-

Advertisements for surrogate mothers.

SURROGATE Mothers Needed. Bring joy to a childless couple. Artificial insemination. Must be healthy, over 21, given birth to healthy child(ren). Medical expenses paid. Living expenses of $10,000 pd. 415-*///*-*////*. Hager Institute. Asians needed. Atty.

SURROGATE MOTHER needed by married couple. Single, healthy and mature preferred. Write P.O. Box *////*, Madison, WI 53706.

SOURCES: *San Francisco Chronicle; University of Wisconsin Badger Herald.*

tended rearing parents, depending upon the nature of the commercial arrangement.

The extent of such medical responsibilities may be greater than some physicians might imagine. For example, an intrafamilial surrogacy arrangement in 1987 ended in calamity when physicians screened the sperm donor for human immunodeficiency virus, but not his sister-in-law, the surrogate mother. Neither the sperm donor nor his wife suspected that the wife's sister had been an intravenous drug user nearly 5 years beforehand, and the physicians' medical history failed to elicit this fact. Five months into the pregnancy, the surrogate mother underwent testing and was shown to be seropositive, as was the baby when it was born. Neither the surrogate mother nor the intended rearing parents wished to take custody of the baby (20). Physician liability in such a situation is unclear.

With the introduction of court-ordered and contractually limited behaviors by women, such as refraining from alcohol or submitting to cesarean section (discussed later in this chapter), physicians may find themselves with a novel duty—to adequately screen surrogate mothers for their potential willingness to abide by such directions. OTA identified at least 10 matching services that do some sort of psychological screening before the surrogate mother attempts a conception.

Psychiatrists are familiar with the duty to predict patient behavior and to warn potential victims of a patient's likely misdeeds (66). This is generally restricted, however, to circumstances in which there is an identifiable person at risk of physical violence, and it is unclear if such a doctrine could extend to victims of a breach of contract.

With the widespread use of contractual arrangements for collaborative reproduction, involving large sums of money and emotionally charged arrangements, efforts may be made to hold physicians liable for inadequate psychiatric screening should contracts be breached by surrogate mothers or intended rearing parents. This is not only because the parties are likely to identify the physician as one of the persons who could have avoided the difficulties by adequate screening, but also because physicians generally have generous malpractice insurance coverage, and therefore may be viewed as "deep pockets" from whom to obtain damages.

One example of the kind of practice that might lead to suits is a physician's choice not to screen for women who are unlikely to be able to relinquish the child at birth (24). Such practice might leave psychiatrists vulnerable to charges from the intended parents that inadequate precautions were taken to ensure the smooth operation of the contract.

Services offering surrogate gestational mother matching may find that their physicians have an additional area of responsibility, this time with respect to the transferred embryos. The Louisiana IVF statute (see ch. 13) grants in vitro embryos certain legal rights ordinarily accorded only to live-born children, such as the right to bring suit through a legal guardian, and places specific responsibilities upon physicians to guard the embryo from harm. The combination of these two principles could enormously expand the potential liabilities of physicians subject to that or any other similar law.

Attorneys

About 25 percent of the surrogate matching services surveyed by OTA have an attorney on staff; others generally have a regular attorney to whom they can refer surrogates and clients. Inhouse attorneys are usually used to represent the clients, rather than the surrogates. Attorneys negotiate terms of the surrogacy contract, advise clients of the likelihood that the contracts are legally and practically enforceable, handle any legal action necessary to enforce provisions of the contract, supervise the transfer of funds and of medical or expense payments to the surrogate, and manage the postbirth details concerning relinquishment of parental rights by the biological mother, transfer of custody to the biological father, and adoption by the father's wife.

Attorneys generally owe a duty of professional service and confidentiality to their clients and to no others. For this reason, every State has ethics rules that forbid an attorney from representing two parties whose interests may conflict. Thus, an attorney who represents both the surrogate mother and any other party to a surrogate arrangement without obtaining appropriate permissions from both parties may be subject to professional discipline by the State bar, as well as to malpractice suits by the affected clients. Surrogate matching agencies uniformly reported that their attorneys do not routinely represent both clients and surrogates, but one agency does state that this can happen if all parties make such a request. Nor can an attorney who represents infertile couples arrange to refer all prospective surrogates to a particular attorney, with whom he or she splits a fee. Such fee-splitting arrangements are forbidden in most States as prejudicial to the interests of the person being referred. Nevertheless, at least one matching service routinely refers surrogates to a particular attorney (30).

In addition, most States have ethical codes forbidding attorneys from drawing up contracts that they know are illegal, unenforceable, or coercive. This poses a problem for attorneys working in a novel field, such as surrogacy, as it may be unclear at the outset whether the contracts are legal and enforceable in any particular State. To date, no attorney has been subject to disciplinary proceedings for developing surrogacy contracts.

Who Becomes A Surrogate Mother?

OTA asked surrogate matching agencies to describe some of the characteristics of the women who had passed through their screening procedures and were waiting to be hired as surrogate mothers. On average, they were women of 26 to 28 years of age, almost all heterosexual, and approximately 60 percent of them married. Almost 90 percent of the women waiting to be hired through the agencies surveyed are reported to be non-Hispanic whites, approximately two-thirds Protestant, and nearly one-third Catholic (see table 14-1).

All but one of the agencies reported that all its surrogates had had a prior pregnancy, and overall the agencies reported that approximately 20 percent of the surrogates had had either a miscarriage or an abortion in the past. Generally fewer than 10 percent of the women had previously relinquished a child through adoption, and overall the agencies reported that fewer than 7 percent of the women were acting as surrogates for the second time. Agencies reported that approximately 12 percent of the women were themselves adopted.

Overall, agencies reported that fewer than 35 percent of the women had ever attended college, and only 4 percent had attended any graduate school. Agencies draw the bulk of the surrogates from the population earning $15,000 to $30,000 per year (approximately 53 percent), with 30 percent earning $30,000 to $50,000 per year, and at most 5 percent earning more than $50,000. Six agencies reported no women earning less than $15,000 per year who were currently waiting to be hired as surrogates, partly due to the fact that some agencies will not accept surrogates who are on welfare or who are not "financially independent." Overall, agencies reported that approximately 13 percent of the women had household incomes of less than $15,000 per year.

REQUIRING CONSENT FROM THE HUSBAND OF THE SURROGATE MOTHER

Many surrogate contracts are written to include consent by the surrogate's husband, even though no State law requires it (9,11,12). Other contracts, such as the one used in the *Baby M* case, require both the husband's consent to the surrogacy arrangement and his explicit statement that he does not consent to the insemination. This fiction is designed to obviate the State's automatic presumption of the husband's paternity, which applies when a husband consents to his wife's insemination with donor sperm. (See ch. 13 for a description of the effect of husband's consent on presumptions of paternity.)

Even if a husband were required by State law to consent to his wife's agreement to be a surrogate mother, it would be difficult to enforce. Of course, failing to get consent would probably serve as grounds for divorce, whether as a novel interpretation of adultery or as emotional cruelty.

However, as grounds for divorce are no longer needed in most States, and as property distributions are largely made with little regard for marital misconduct, this enforcement mechanism means little (21). The only effective way to enforce such a requirement would be to direct penalties at the professionals associated with arranging these contracts, namely the commercial brokers,

Table 14-1.—Demographic Surveys of Surrogate Mothers

	OTA[a]	Linkins[b]	Hanifin[c]	Parker 1[d]	Parker 2[e]	Franks[f]
Sample size	>334[1]	34	89	30	125	10
Average age	27	28	28	25	25	26
Marital status:						
Married	60%	73%	80%	87%	53%	50%
Single	40%[2]	18%	14%	10%	19%	40%
Divorced		9%	5%	3%	22%	10%
Unknown					6%	
Number of children	*	1.8	2.0	1.9	1.4	1-3
Race/ethnicity		*				*
White non-Hispanic	88%		85%	100%	100%	
Hispanic	2%		14%			
Black non-Hispanic	<1%		<1%			
Asian	2%		<1%			
Other	8%[3]		<1%			
Religion		*				*
Protestant	67%		74%	53%	55%	
Catholic	28%		25%	47%	40%	
Jewish	3%		<1%		1%	
Other	2%		<1%		4%	
Household income			*	*		
<$15,000	13%	*			*	*
$15,000-$30,000	53%	*			*	*
$30,000-$50,000	30%	*				
>$50,000	4%	*				
Average	*	$18,000			*	*
Range	*	$5K-$68K			$6K-$55K	(modest-moderate)
Education						
Some high school	61%[4]	12%		20%	18%[5]	
High school graduate		38%	52%	53%	54%[5]	(average for sample)
Some college	35%[4]	47%	24%	27%	26%[5]	
College graduate		3%[6]	24%[6]		2%[5]	
Some graduate school	4%[4]					
Previously:		*				*
Was surrogacy mother	7%		*	*	*	
Gave up child for adoption	7%		1%	10%	9%	
Had abortion or miscarriage	20%		37%	23%	26%	
Are themselves adopted	12%	*	1%	1%	1%	*

*Not applicable or unavailable.

[1] Data supplied by matching agencies, not by surrogates themselves.

[2] Includes divorced.

[3] May include Hispanics.

[4] Includes graduates.

[5] Includes only 50 women in sample.

[6] Includes category "some graduate school."

SOURCES:

[a] Office of Technology Assessment, 1988.

[b] K. Linkins, H. Daniels, R. Richards, and D. Kinney, McLean Hospital, Belmont, MA, personal communication, Feb. 9, 1988.

[c] H. Hanifin, *The Surrogate Mother: An Exploratory Study* (Chicago, IL: University Microfilms International, 1984); H. Hanifin, "Surrogate Parenting: Reassessing Human Bonding," presented at the Annual Meeting of the American Psychological Association Convention, New York, August 1987.

[d] P.J. Parker, "The Psychology of the Surrogate Mother: A Newly Updated Report of a Longitudinal Pilot Study," presented at the American Orthopsychiatric Association General Meeting, Toronto, Apr. 9, 1984.

[e] P.J. Parker, "Motivations of Surrogate Mothers: Initial Findings," *American Journal of Psychiatry* 140:117-118 (1983).

[f] D.D. Franks, "Psychiatric Evaluation of Women in a Surrogate Mother Program," *American Journal of Psychiatry*, 138:1378-1379 (1981).

physicians, and attorneys. To consider the contract itself unenforceable absent the consent is another possibility, although it might lead to the undesirable result that a child is left without clearly identifiable legal parents.

RECORDKEEPING AND CONFIDENTIALITY

Births are ordinarily registered by having a birth certificate filled out in the hospital. The mother's name is entered, as is the name of her husband or the reported father of the child. Absent a court order, it is not possible to substitute an adopting mother's name on a birth certificate. Just such court orders have been used, however, for surrogate arrangements. In one case a birth mother refused to terminate her parental rights, so the genetic father dropped his custody suit in exchange for a court order to place his name on the birth certificate (31). In another case, a Michigan court entered an order that an ovum donor and her sperm donor husband should have their names entered on the birth certificate of the child borne for them by a woman hired to be the child's gestational mother (63). The same was done a year later by a California court (62).

A Massachusetts couple has asked a Virginia court to do the same for them with respect to a baby born on December 21, 1987, to a surrogate gestational mother (17). These cases are notable because it is a new development in law to settle by either contract or court order, prior to birth, the identity of the legal parents whose names will appear on the birth certificate.

The only State law as of early 1988 that addresses this problem in the context of surrogate motherhood is Arkansas Statute Section 34-721, which states:

> For birth registration purposes, in cases of surrogate mothers, the woman giving birth shall be presumed to be the natural mother and shall be listed as such on the certificate of birth, but a substituted certificate of birth can be issued upon orders of a court of competent jurisdiction.

Thus, even in Arkansas, a court order is needed to issue a birth certificate with the name of the woman who intends to raise the child.

Adoptees argue they have a right to know the identity of their birth parents (55), claiming that issuing birth certificates with adoptive parents' names unconstitutionally discriminates against adoptees and violates their right to privacy. (See ch. 12 for discussion of the right to privacy.) Their arguments have been unsuccessful, so it seems unlikely that children of surrogates will have any more luck objecting to State procedures to guard the identity of their birth mothers. However, many States have passed legislation to provide adoptees with nonidentifying information concerning the health, interests, and ethnic background of their biological parents (56), and such State statutes could be held to apply or could be extended to cover children of surrogacy arrangements.

Absent legislative protections, children conceived by surrogacy will have no recourse but to their rearing parents for information about the women who gave birth to them. All but one agency surveyed allow clients and surrogates to meet and to have contact during and after the pregnancy, if it is mutually desired. Four agencies will supply names and addresses, while others presumably arrange meetings at their offices. Only one surveyed agency has a strict policy of mutual anonymity.

TYPICAL CONTRACT PROVISIONS

Fees

As reported to OTA, the most common fee for a surrogate mother is $10,000 plus expenses for life insurance, maternity clothes, required transportation to the matching center or physician, necessary laboratory tests, and the delivery, a figure that has not changed since 1984 (2,14), although two agencies reported a fee of $12,000 and three stated that each fee is negotiated individually. In addition, fees are paid to the commercial broker who found the surrogate and matched her to the couple seeking a child (commonly between $3,000 to $7,000, but ranging up to $12,000); to the physicians who examine the parties and perform the artificial insemination (from $2,000 to $3,000); to the psychiatrist or other psychological counselor (from $60 to $150 per hour); and to the attorneys who counsel the parties, draw up and negotiate the contract, and arrange for the proper adoption procedures to be followed after the child's birth (up to $5,000). The total cost of all these fees and expenses can be roughly $30,000 to $50,000, meaning that about $1 of every $4 actually goes to the surrogate mother herself.

At least 36 States make it illegal to induce parents to part with offspring or to pay money beyond medical, legal, and certain other expenses to give a child up for adoption. Some 12 statutes specifically make it a crime to offer monetary inducements beyond medical expenses. Although not clearly criminal, the statutes in the other 24 States could render voidable the surrogate mother's agreement to relinquish rearing rights and duties in exchange for such inducements.

Whether these statutes will be applied to surrogate transactions is uncertain and will depend upon judicial decisions in each State affected, as well as upon interpretations of State and Federal constitutional protections of the right to procreate. The agreement is entered into before conception or implantation, and thus lacks any coercive pressure from unwanted pregnancy or recent childbirth. It is the influence that these pressures might have on the ability to make a truly voluntary decision, coupled with concern over child placement, that underlies the many State laws against exchanging funds for a baby (36). Furthermore, one can argue that the money is paid to the surrogate for her service: "The biological father pays the surrogate for her willingness to be impregnated and carry his child to term. At birth, the father does not purchase the child. It is his own biological genetically related child. He cannot purchase what is already his," stated the *Baby M* trial court (30). Some contracts are written to pay the mother a monthly fee, rather than a lump sum upon relinquishment of the child, perhaps to enhance the impression that it is her services that are being bought, not the baby (15).

On the other hand, the agreement to relinquish custody and parental rights at birth is a central part of the surrogate's bargain. The hiring couple has no interest in obtaining her services unless she will relinquish the child at birth. If she does not relinquish her parental rights, generally no fee is paid. Furthermore, reports to OTA and other sources indicate a miscarriage often results in only a nominal fee being paid, ranging from nothing to $3,000 (24). A stillbirth can result in no fee at all in at least two centers, with two others paying only a portion of the fee (37), all further giving the impression that these contracts are in fact a direct exchange of funds for exclusive custody and parental rights to a baby.

In addition, at least two centers reduce or eliminate the fee entirely if the surrogate is found to have behaved in a way that caused a health problem in the child, furthering the parallel between the transfer of the baby and the transfer of manufactured property. The Kansas Attorney General, considering this point, concluded "we cannot escape the fact that custody of the minor child is decided as a contractual matter" involving the exchange of funds, which violated public policy that "children are not chattel and therefore may not be the subject of a contract or a gift" (35).

If the State laws prohibiting monetary inducements to adoption are deemed applicable to paid surrogacy, they would make payment of money to surrogates illegal baby-selling. For example, an Indiana court held that paid surrogacy violated both the letter and policy of Indiana's statute prohibiting the exchange of funds beyond expenses for any adoption (46), as did the New Jersey Supreme Court in the 1988 *Baby M* case (30).

Similarly, a 1983 case stated that Michigan law prohibits paid surrogacy, and furthermore that such a prohibition does not violate the fundamental right to bear children (16). The court noted that the prohibition on payment does not forestall medically assisted pregnancy, adoption, or even unpaid surrogacy. Instead, in the court's view, the prohibition legitimately protects children from becoming articles of commerce. Of course, decisions holding baby-selling prohibitions applicable to surrogacy arrangements might adversely affect the interests of some children if the result is that rearing parents forgo the necessary steps to ensure adoption by the nonbiological mother in order to avoid judicial scrutiny of the underlying surrogacy agreement.

The New York and Kentucky courts, unlike those in Indiana, Michigan, and New Jersey, have held that their State baby-selling prohibitions do not specifically address the situation created by surrogate motherhood, and that therefore payments are allowable until the State legislature decides otherwise (29,64). The fact that the transfer of custody is between biological parents influenced these decisions, as it makes the arrangement one of payment for exclusive custody and termination of parental rights, rather than the classic baby-selling envisioned in most State laws.

In 1987, amendments to Nevada's adoption law exempted "lawful" surrogacy contracts from the provisions of Nevada's statute prohibiting payment to a mother beyond her expenses (Nevada Revised Statutes, ch. 127). It should be noted, however, that the law still invalidates a mother's consent to relinquish a child for adoption if made less than 48 hours after birth. It is not clear whether a surrogacy contract that commits the mother to relinquish the child is in and of itself a violation of the law, making the contract "unlawful" and therefore outside the provisions of this amendment. Further, the statute is not clear on how the courts should balance the competing provisions of the contract terms and the statutory 48-hour cooling-off period, should there be a dispute. Although the intent of the amendment clearly seems to be to exempt surrogacy from the prohibitions on baby-selling, it is not clear whether the amendment is also intended to render surrogacy agreements fully enforceable.

Whether prohibitions on exchanging money for termination of parental rights and custody are held to make surrogacy arrangements criminal or merely unenforceable, they would effectively prevent surrogacy from becoming a freely available alternative to adoption, since few nonrelated women will be surrogates on altruistic grounds (51,52). The constitutionality of such a ban on paid surrogacy remains to be determined by most States and by the Federal courts.

Limitations on Behavior During Pregnancy

Typical contract provisions reported to OTA and other sources include prohibitions on smoking, alcohol, and illegal drugs (2,9). Some may go further and consider types of permissible exercise or diet. A practical problem with provisions such as these is the difficulty of enforcement. It is hardly feasible to follow a woman around to observe or control her behavior. A more general problem is that such contract provisions, particularly if they were required by State law, could unconstitutionally interfere with individual rights to privacy, personal autonomy, and bodily integrity (see ch. 12).

An alternative enforcement mechanism is to sue for breach of contract should the mother fail to abide by these restrictions. However, it is unlikely that any minor breach of these behavioral restrictions will lead to an identifiable health problem in a child, leaving it unclear how to assess damages. Even damages agreed upon in advance for breach of a contractual provision (known as "liquidated damages") cannot be used unless the figure set for the damages bears some reasonable relationship to the harm caused by the breach. Thus, both prenatal efforts to enforce the behavioral lifestyle restrictions or postnatal attempts to collect damages for their breach are difficult propositions.

However, a pregnant woman may possibly have a noncontractual duty to prevent harm to her fetus (59), regardless of whether she intends to raise the child. This is a controversial and developing area of law, and a number of commentators have expressed concern that the identification of such a duty might unconstitutionally limit women's bodily autonomy (5,18,22,23,33,34). A few courts have held that women not only may have an obligation to refrain from harmful behaviors—such as taking drugs—but may also have an obligation to take affirmative steps to prevent harm, such as undergoing cesarean sections (58).

Surrogate motherhood arrangements could affect the development of this evolving area of law because the pregnant woman is often unrelated to the intended rearing parents of the child. The couple generally invest a great deal of time and money in trying to ensure that they will raise the child she bears. They might conceivably be less reluctant to use legal methods to try and control her behavior.

Limitations on Control Over Medical Decisions

Typically, the surrogate agrees in the contract to abide by her physician's orders. Such orders can extend to whether or not to undergo amniocentesis, electronic fetal monitoring, or a cesarean delivery. Further, two-thirds of the agencies surveyed report that their contracts allow the client to exercise some control over whether the surrogate mother will undergo chorionic villi sampling, amniocentesis, or abortion, as well as the type of prenatal care she will receive. Placing such provisions in the contract gives the client the possibility of more extensive control over the surrogate mother's pregnancy, as it gives the client another basis upon which to go into court to seek an injunction to force her to comply or to seek damages should she refuse to comply. Principles of personal autonomy probably prevent the enforcement of any requirement to undergo amniocentesis or abortion, and many proposed State laws would prohibit enforcement of such clauses. But a surrogate's refusal to comply with these requests might serve as a justifiable cause for breaking the contract and requiring the return of any monies received.

In the *Baby M* case, the trial court stated in dictum that such clauses are not specifically enforceable, but did not state whether any form of monetary damages would be owed (30). "Specific enforcement" or "performance" is a judicial remedy for breach of contract. It means that the court orders that the terms of the agreement be carried out, rather than that monetary damages be paid. Here, specific performance refers to ordering the woman to submit to amniocentesis or abortion, something that raises constitutional questions concerning her right to bodily integrity and autonomy. With respect to other aspects of surrogate contracts, it could refer to relinquishing custody and parental rights. It could also be used to try to enforce an agreement not to smoke or drink or work in the presence of toxic materials. Specific performance is rarely ordered for these last types of promises, as it is virtually impossible to ensure compliance (19).

The contractual arrangement with the surrogate mother and the evidence of intent to rear the child might be used by the client, however, to argue that he and his partner have standing to seek an injunction ordering the mother to undergo a medical procedure such as a cesarean section. "Standing" generally means the right to be a plaintiff in a suit before a court. Only persons who have a legally recognizable interest in the case are granted standing. This is particularly important in light of the controversy surrounding the use of court orders to force women to undergo cesarean sections because their physicians or husbands disagree with their decision to forgo the procedure (41,58). How the courts might react in the contractual surrogacy situation, however, is difficult to predict, as is the extent to which judicial decisions would be taken to apply equally to women who intend to raise the children they bear.

Choice-of-Law Provisions

Some contracts used by the surveyed agencies provide that disputes will be resolved by courts located in a particular jurisdiction or by application of the laws of a particular State. Such provisions are important, as the arrangements often involve participants and brokers from different States. State court decisions vary concerning the acceptability of paid surrogacy and the enforceability of the contracts, as do individual State law provisions concerning the mechanics of adopting a child or identifying legal paternity of a child conceived by artificial insemination. Thus, the outcome of a dispute concerning a surrogacy arrangement could depend largely upon which State's laws are applied.

In any litigation involving parties from different States, often the first task facing a court is to decide which court should hear the case and which State's laws should be applied. Contract provisions can often, but not always, be used to settle these questions before a dispute has arisen (42).

This is particularly important with respect to disputes concerning custody of a child, as delays could affect the amount of time the child spends with one of the parents, in turn affecting the court's willingness to change the child's custodial parent. For example, the New Jersey Supreme Court explicitly noted in its *Baby M* decision that court orders should no longer be issued in New Jersey to force a woman to relinquish a baby, even temporarily, pursuant to a surrogacy contract (30).

With the passage of conflicting legislation in Arkansas and Louisiana—with one State facilitating and the other inhibiting commercial surrogacy—choice-of-law questions have gained importance. This is particularly relevant since every service surveyed by OTA said it had matched surrogates and clients from different States, at least nine services had made matches with surrogates or clients outside the United States, and two services had tried to open branches in Europe (37,38,67).

The Surrogate Mother's Rights to the Child

Surrogate contracts typically require the mother to immediately relinquish custody of the newborn baby. (Only three agencies do not use this provision, each reporting that it would appear to be unenforceable under State law.) She then is required to sign papers terminating her parental rights. Custody and parental rights are different: A parent may have the right to visit his or her children without having the right to live with them. Terminating parental rights means terminating visitation, intervention in the education and training of the child, and indeed all rights to the child. Legally, the parent becomes a stranger to the child. The same is true in the case of more ordinary forms of adoption, although there has been considerable legislative activity in the States to provide children and their biological parents the opportunity to learn each other's identity if mutually desired, and in some cases to give adopted children access to nonidentifying medical information concerning their biological parents (55,56).

Almost all surrogacy contracts provide that the genetic father will take custody regardless of the sex or health of the child, and that his wife will assume custody if he should die. (At least one service, however, writes contracts that do not require the genetic father to take custody if the child is born with a health problem that seems to be the result of some action by the surrogate mother; it is not clear that such an exemption is valid under State law.) If both intended parents die before the birth of the child, the surrogate mother could keep the baby or put the child up for adoption.

As indicated earlier, a central issue in surrogacy is whether a contract can determine custody and parental rights when the surrogate mother refuses to relinquish either. Courts and attorney general opinions have consistently stated in dictum that a surrogate mother has all the same rights to her child as does a mother who conceived with the intention of keeping her baby. In other words, in the event of a custody dispute between the genetic father and surrogate mother, both would stand on equal footing and the best interests of the child would dictate the court's decision (29, 35,44,46,49,64). The courts reasoned that a surrogate motherhood contract, while not void from inception, is nevertheless voidable. This means that if all parties agree to abide by the contract terms, and the intended rearing parents are not found to be manifestly unfit, then a court will enter the necessary paternity orders and approve the various attorney's fees agreed upon (29). If, on the other hand, the surrogate mother changes her mind about giving up her parental rights within the statutory time period provided by the applicable State law, then "[s]he has forfeited her rights to whatever fees the contract provided, but both the mother, child and biological father now have the statutory rights and obligations as exist in the absence of contract" (64).

Until the *Baby M* (30) and *Yates v. Huber* (69) cases, no custody dispute ever made it to trial in the United States (see app. E for a description of events in other countries). In both of these 1988 decisions, however, surrogate motherhood contracts were voided, and held irrelevant to determining custody of a child wanted by both the surrogate mother and the genetic father. The New Jersey decision, particularly important because it comes from the highest court in the State, went further than many of the prior advisory opinions, and held that commercial surrogacy contracts are void (and possibly criminal), not merely voidable.

Finding the contract void has several important consequences. First, as noted earlier in this chapter, it removes an important basis on which a court could order a surrogate mother to relinquish a child to the genetic father pending resolution of a custody dispute. Second, it eliminates the contractual authority of a genetic father to control the behavior of a surrogate mother during pregnancy, or to specify the conditions of her prenatal care and delivery. Finally, it makes a surrogacy contract unenforceable, so that courts would not be allowed to order even monetary damages for its breach. This complete lack of enforceability could be a tremendous deterrent to the further popularization of surrogate motherhood, although it should be noted that similar unenforceability with regard to prenatal independent adoptions has not eliminated that practice. The *Baby M* decision only applies to cases decided under New Jersey law, of course, but its reasoning may be influential in many other States.

The *Baby M* reasoning was based on three factors. First, the New Jersey Supreme Court found that the contract conflicted with laws that prohibit exchange of funds in connection with adoption, dismissing arguments that the payments were for a surrogate's services. Second, the contract violated State statutes under which parental rights may only be terminated for parental unfitness or abandonment, as well as case law holding that parents may not agree between themselves by contract to terminate rights or determine custody of a child, noting that such laws are designed to ensure that a child's best interests, rather than the wishes of parents, are paramount at all times. Finally, the court held that the contract violated State law making a parent's consent to adoption revocable for a certain time period following birth.

The same reasoning with regard to consent for adoption has been used by other State courts. Permission to adopt a child is not valid if given before birth (see table 14-2), leading a number of courts to state that this would bar specific performance of the custody and termination of parental rights provisions of surrogacy contracts (29, 46,64). Acknowledging that the surrogate's consent to adoption is made before conception, and therefore not under the duress of an unintended pregnancy (36), the New Jersey Supreme Court nevertheless stated:

> The natural mother is irrevocably committed before she knows the strength of her bond with her child. She never makes a totally voluntary, informed decision, for quite clearly any decision prior to the baby's birth is, in the most important sense, uninformed, and any decision after that, compelled by a pre-existing contractual committment, the threat of a lawsuit, and the inducement of a $10,000 payment, is less than totally voluntary (30).

Informed consent to engage in a surrogacy arrangement is made even more problematic in transnational surrogacy arrangements, where language barriers, absence of legal counsel, and immigration considerations may affect the transaction. For example, one surrogacy contract between an American couple and a Mexican woman who is second cousin to the infertile wife has resulted in a custody dispute complicated by allegations of misunderstanding and violations of immigration law. The surrogate mother has said that she understood that she was to be impregnated by artificial insemination and that the embryo was then to be transferred to the uterus of the infertile woman. The couple asserts that the handwritten contract and oral understandings always contemplated a full-term pregnancy, with the child relinquished to the genetic father and his wife at birth. In exchange, the couple was to provide clothing, medical care, food, and assistance at obtaining a visa for permanent residency in the United States (27,67).

The arrangement was complicated by the fact that it included providing housing in the United States for the Mexican mother, in violation of immigration regulations. The case has had preliminary hearings in U.S. courts, and temporary custody was awarded to the couple, with visitation rights granted to the surrogate mother. Transnational contracts such as these, made difficult by language problems (the surrogate mother in this case spoke no English and was not represented by an attorney) and the vulnerability of women hoping to enter the United States from poorer

Table 14-2.—State Adoption Laws

State/jurisdiction	Prohibit payment beyond expenses	Permission to adopt invalid before birth[a]	Adoption agencies must be licensed
Alabama	x	x	x
Alaska		x	
Arizona	x	x	x
Arkansas	x	x	
California	x	x	x
Colorado	x	x	
Connecticut		x	x
Delaware	x	x	x
District of Columbia		x	
Florida	x	x	
Georgia	x	x	x
Hawaii		x	
Idaho	x	x	
Illinois	x	x	x
Indiana	x	x	
Iowa	x	x	
Kansas	x	x	
Kentucky	x	x	x
Louisiana	x	x	
Maine	x	x	
Maryland	x	x	x
Massachusetts	x	x	x
Michigan	x	x	
Minnesota		x	x
Mississippi	x	x	
Missouri	x	x	
Montana	x	x	
Nebraska		x	x
Nevada	x[b]	x	x
New Hampshire		x	
New Jersey	x	x	x
New Mexico		x	
New York	x	x	x
North Carolina	x	x	x
North Dakota	x	x	
Ohio	x	x	x
Oklahoma	x	x	x
Oregon		x	
Pennsylvania	x	x	
Rhode Island		x	
South Carolina	x	x	
South Dakota	x	x	
Tennessee	x	x	x
Texas	x	x	
Utah	x	x	
Vermont		x	
Virginia		x	
Washington		x	x
West Virginia		x	
Wisconsin	x	x	x
Wyoming		x	

[a] Includes statutory and judge-made law

[b] Surrogate mothering exempt from prohibition by 1987 act of legislature

SOURCES: National Committee for Adoption, *Adoption Factbook: United States Data, Issues, Regulations, and Resources* (Washington, DC: 1985); J. A. Robertson, "State Statutes on IVF, Artificial Insemination, and Surrogate Motherhood," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1986.

countries, are particularly subject to attack. In fact, in this particular case, the contract claims were dropped by the couple, and the custody dispute was heard in family court.

Adoption

Surrogacy contracts usually require an adoption by the genetic father's spouse. In some States, the genetic father may already be identified as the legal father (e.g., by a judicial finding of his uncontested paternity) and thus able to initiate expedited stepparent adoption proceedings for his wife. A number of States have special procedures for stepparent adoptions that expedite adoption waiting periods and avoid the use of adoption agencies. In other cases, the genetic father and his wife will both have to adopt the child, requiring a series of home inspections, references, and court approvals (47).

As some States do not allow anyone but a husband to bring a suit to counter the presumption of his paternity (12,25,61), a genetic father and his wife may be faced with a tremendous difficulty in the event that the surrogate is married, and she and her husband refuse to relinquish the child. By not allowing a challenge to be brought to his presumed paternity, the surrogate mother's husband could thwart the genetic father's attempts to establish his own paternity in order to contest custody of the baby.

Courts might avoid this result by not reading such laws literally when a husband consents to his wife being inseminated as part of a surrogate transaction but does not consent to assuming rearing rights and duties for offspring. Such a result is most likely in New Jersey, New Mexico, and Washington, which specifically allow the parties to agree separately about donor rights and duties. However, other jurisdictions might also reasonably find that the artificial insemination laws were not intended to regulate surrogate inseminations. For example, the "sperm donor" in a surrogate situation is in fact not donating sperm for pay or altruism, but with the intention of taking custody of any resulting child. Courts might find that such persons are not "sperm donors" for the purpose of artificial insemination statutes.

One State law attempts to avoid some of these difficulties. Arkansas Statute Section 34-721(B) states:

> A child born by means of artificial insemination to a woman who is unmarried at the time of the birth of the child, shall be for all legal purposes the child of the woman giving birth, except in the case of a surrogate mother, in which event the child shall be that of the woman intended to be the mother.

This provision avoids the complications of adoption by declaring the intended rearing mother to be the child's legal parent. Thus, if all parties agree to fulfill the contract terms, the surrogate mother's rights should be cut off in favor of the intended rearing mother, without the need to get a court order or approval.

The statute is unclear, however, on certain points. First, by its terms it applies only to unmarried women, leaving open the question of the child's legal parentage if the surrogate is married. (In 1987 a bill to extend the provision to married women was passed by the Arkansas legislature but vetoed by the Governor.) Section 34-721(A) of the statute states without reservation that a child born by artificial insemination to a married woman is presumed to be her husband's child. Second, the statute concerns "presumptions" of legal parenthood. Unless clearly stated otherwise, presumptions are generally rebuttable. The statute does not address the problem of a surrogate mother changing her mind and deciding to retain parental rights, and it is unclear whether this statute would automatically cut off her rights should she choose to rebut the presumption. Artificial insemination statutes concerning paternity are similarly written in terms of "presumption of paternity," and those presumptions are rebuttable under certain circumstances—for example, if the husband can show that he did not consent to the insemination. The reasons for which a surrogate mother can rebut the presumption of maternity are not stated in the Arkansas law.

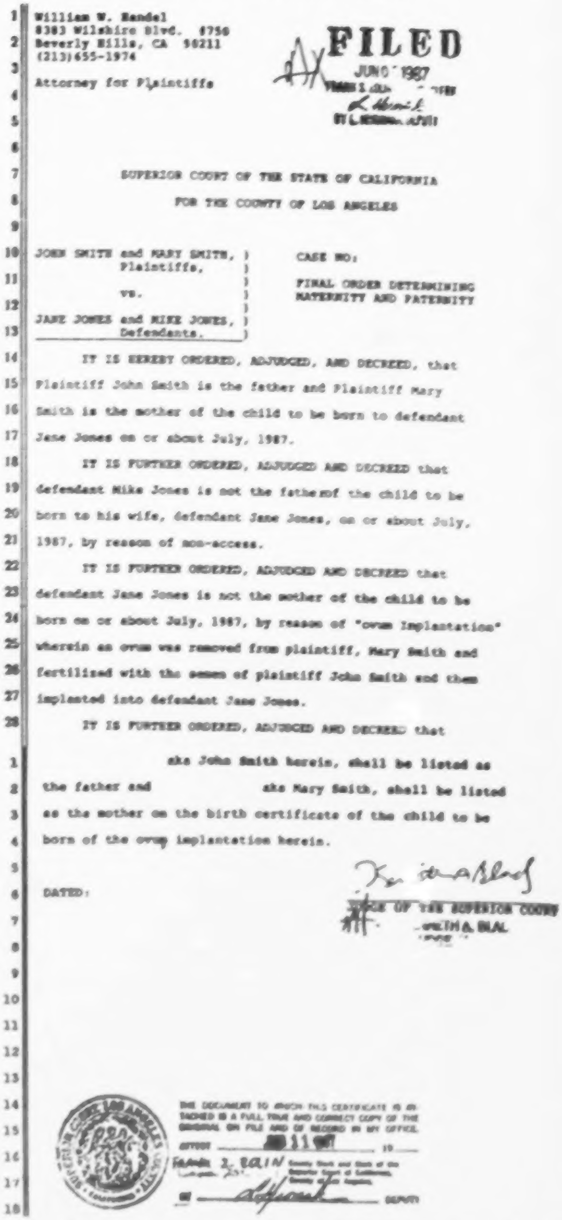
THE SURROGATE GESTATIONAL MOTHER

For many years, a woman who bore a child was clearly the mother of that child, a doctrine recently expressed in classical fashion as *mater est quam gestatio demonstrat* ("the mother is demonstrated by gestation") (45). This certainty is no longer unequivocal. The separation of biological motherhood into genetic and gestational components opens the door to fresh legal consideration of the crucial aspect of motherhood that entitles a particular woman to *a priori* rights to a child. The developing law of surrogate motherhood may not help, as it pits the rights of a genetic and gestational mother against the rights of a genetic father, with an underlying preconception agreement between the two as a key factor. Surrogate gestational motherhood concerns somewhat different relationships. The two factors of similarity, however, are the existence of an underlying agreement that reflects the intentions of the parties, and the surrogate mother's experience of pregnancy.

Women who are unable to carry a pregnancy to term, whether due to disease (such as certain forms of diabetes), physical handicap, or repeated idiopathic miscarriage, may wish to have an alternative to adoption. To have a child to whom they are genetically related, one developing although still rather rare option is the employment of a surrogate gestational mother, in whom is implanted an embryo conceived with the sperm and egg of the intended rearing parents. Women who carry to term babies to whom they are not genetically related, and who intend to relinquish the child at birth to the genetic mother, may have fewer rights with respect to the child than do the surrogate mothers who are genetic as well as gestational parents. Their lack of a genetic connection, combined with their original intent to bear the child for someone else, may work to deny them equal footing with the baby's genetic parents should a custody dispute arise.

A further consideration in this area is that this technique could be used to allow Caucasians to hire non-Caucasians from this country or abroad to bear babies. Concern has been expressed that, particularly with surrogates drawn from developing countries or the American underclass, the technique could be used to lower costs for the intended rearing parents, as payments of far less than $10,000 would nevertheless constitute a considerable sum to the surrogate gestational mother (28). Of course, as the technique requires sophisticated medical procedures to transfer the embryo from the ovum donor or petrie dish to the gestational mother, it is likely to have limited application. Nevertheless, it could be used, and some fear abused (13). The problems arising from the Mexican-American surrogacy contract previously discussed illustrate some of the possible areas for abuse.

Pre-Birth Judicial Order



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FILED
JUN 0 1987

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

JOHN SMITH and MARY SMITH,
Plaintiffs,
vs.
JANE JONES and MIKE JONES,
Defendants.

CASE NO:

FINAL ORDER DETERMINING MATERNITY AND PATERNITY

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED, that Plaintiff John Smith is the father and Plaintiff Mary Smith is the mother of the child to be born to defendant Jane Jones on or about July, 1987.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that defendant Mike Jones is not the father of the child to be born to his wife, defendant Jane Jones, on or about July, 1987, by reason of non-access.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that defendant Jane Jones is not the mother of the child to be born on or about July, 1987, by reason of "ovum Implantation" wherein an ovum was removed from plaintiff, Mary Smith and fertilized with the semen of plaintiff John Smith and then implanted into defendant Jane Jones.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that aka John Smith herein, shall be listed as the father and aka Mary Smith, shall be listed as the mother on the birth certificate of the child to be born of the ovum implantation herein.

DATED:

JUDGE OF THE SUPERIOR COURT

THE DOCUMENT TO WHICH THIS CERTIFICATE IS ATTACHED IS A FULL, TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE AND OF RECORD IN MY OFFICE.
ATTEST ______ 11 ______ 19 ___
FRANK S. ZOLIN County Clerk and Clerk of the Superior Court of California, County of Los Angeles
BY ______ DEPUTY

This order declares a genetic mother and father to be the legal parents of a child still being carried by a gestational surrogate mother.

SOURCE: Superior Court of the State of California for the County of Los Angeles.

The fact that surrogate mother matching services have been opened in European countries, so that Europeans forbidden under their own laws from the practice (see app. E) might seek a surrogate mother in the United States, indicates that the practice may well soon take on a significant international character.

Whether it is because they are not genetically linked to the fetuses they carry or because they are impoverished or non-American, the rights of surrogate gestational mothers may be diminished as compared with those of other mothers. However, the evidence of their pregnancy and the fact that they gave birth make these women appear to be the babies' "natural" mothers. Thus, their dilemma most clearly poses the question of whether a genetic or gestational relationship, in and of itself, ought to generically determine maternal parentage and legal rights.

One approach is to mimic the law of paternity, by providing that genetic parentage is definitive parentage. This would mean that a genetic mother could apply to a court for a ruling that she is the legal mother of a child being carried to term by another. Such a ruling has been issued at least twice (62,63), although in those cases the orders were made with the consent of all the parties involved and in furtherance of their stated intentions. A similar request was made in 1987 by a Massachusetts couple who had a Virginia woman carry their genetic child to term and relinquish the infant at birth, with a court decision expected in 1988 (17). The very need to resort to a court order, however, indicates that a *de facto* presumption exists that the birth mother is the child's legal mother. In many ways this is analogous to determining paternity, in which a presumption exists that the husband of a pregnant woman is the father of her child, with the presumption rebuttable by evidence that another man is the genetic father.

Another approach is to consider the woman who bears the child as the legal mother, with any further changes in parental rights to be made as per agreement, or in the event of a dispute, as per court order (6). Such an approach implicitly asserts the primacy of the 9-month pregnancy experience as the key factor in designating a "mother." The approach has simplicity as one advantage. For example, hospital officials would always know at the time of birth the identity of the legal mother. This is also the approach taken in the Arkansas statute discussed previously, which addressed the use of birth certificates in the context of surrogate mother agreements.

Of course, such an approach would undercut efforts to regularize surrogate motherhood, as the intended parents would live with uncertainty over whether the birth mother would in fact abide by earlier stated intentions. As the legal mother of the child, the woman giving birth would not be automatically barred from asserting her parental rights. This development might prevent surrogate gestational motherhood from ever becoming widely used, as the uncertainty of the success of the arrangement could dissuade individuals from making the necessary emotional and financial investment. Nevertheless, similar uncertainty surrounds prebirth adoption agreements, which remain an extremely popular way for couples to form a family.

A third approach is to enforce these underlying agreements, regardless of the various genetic, gestational, and intended social arrangements. This would grant the parental rights of motherhood to a genetic mother who intends to rear a child brought to term by another. Such an approach was taken for the first time when the Wayne County Circuit Court in Michigan issued an interim order declaring a gamete donor couple to be the biological parents of a fetus being carried to term by a woman hired to be the gestational mother. The judge also held that the interim order would be made final after tests confirmed both maternity and paternity (40). Upon birth, the court entered an order that the names of the ovum and sperm donors be listed on the birth certificate, rather than that of the woman who gave birth, who was termed by the court a "human incubator" (63).

MODELS OF STATE POLICY

Legislation related to surrogate motherhood has been introduced in over half the State legislatures since 1980 (1,4,32,36,48,53), much of which is still pending. Only Arkansas, Kansas, Louisiana, and Nevada have passed legislation: their approaches have differed, with Arkansas endorsing surrogacy, Louisiana making the arrangement unenforceable, Kansas simply exempting surrogacy from prohibitions on adoption agency advertising, and Nevada exempting it from its prohibition on babyselling. As indicated in chapter 13, the approaches taken by State legislatures may be broadly grouped into categories: static, private ordering, inducement, regulatory, and punitive (14,68). Should Congress choose to follow one of these models, its legislative action would most likely be based on the interstate commerce clause, although conditions on receipt of Federal grants or approval of interstate compacts are other possible routes to Federal involvement (see ch. 1).

The Static Approach

To date, the static approach has had mixed results. While several courts have so far declined to find that surrogates lose their rights of motherhood by virtue of their preconception agreement to relinquish parental rights, most courts have at the same time agreed to enforce the paternity and fee payment provisions of these contracts, at least when all parties to the agreement still desire its enforcement. In other words, although these courts have found surrogate agreements to be voidable, they generally have not found them to be void. A notable exception is the New Jersey Supreme Court, which held that these agreements are void (30).

This socially and psychologically conservative approach seeks to minimize the impact of noncoital reproductive techniques upon the structure and relationships of the traditional family, mainly by refusing to recognize legally new parental configurations. "The family unit has been under severe attack from almost every element of our modern commercial society, yet it continues as the bedrock of the world as we know it. Any practice which threatens the stability of the family unit is a direct threat to society's stability," stated the dissenting justice in *Surrogate Parenting Association, Inc.*, the 1986 case finding that paid surrogate matching services are permissible under Kentucky law. This attitude is typical of the static approach, which aims to support traditional family configurations.

One legislative method for furthering this viewpoint would be the adoption of a definition of "mother" as a woman who gives birth to a child or who obtains a child through a legal adoption proceeding. Such a definition could guarantee surrogate mothers at least those rights held by all mothers with respect to their children and control of their pregnancies.

Although the static approach will undoubtedly slow the growth of surrogate motherhood as an industry, it will not eliminate it entirely. The expansion of these services since 1980, in the absence of judicial or legislative guidelines, demonstrates that this arrangement can be used when all parties abide by their original intentions. There can be some problems with the use of State laws and courts to manage birth certificate recordations and paternity orders, but it is primarily when the parties change their minds that State action becomes important and the absence of governmental guidelines becomes an active barrier to the successful conclusion of the arrangement.

The Private Ordering Approach

The private ordering approach views a government's role primarily as that of facilitating individual arrangements, and thus would compel recognition and enforcement of any conception and parenting agreement freely formed among consenting adults. Such an approach could accommodate commercializing the services of surrogate mothers (14). Private ordering is of course subject to some constraints, for example by allowing special protection of vulnerable parties to the transaction. Children are traditionally viewed as such vulnerable parties, and thus judicial intervention to ensure that custody is awarded to a fit parent would be consistent even with this approach of limited governmental intervention.

Examples of such private ordering philosophy can be found in several of the bills introduced in State legislatures, such as the Nevada amendment that exempts surrogacy from prohibitions on baby-selling. Proposed legislation in Oregon would also follow this model, while another Oregon proposal goes further and specifically legalizes paid and unpaid surrogacy, while providing for specific enforcement and damages as remedies for breach of contract. An early Rhode Island bill also aimed to make surrogacy contracts enforceable, stating that surrogate motherhood "is to be viewed as a business venture," and that the "rights of motherhood" do not apply to the surrogate mother (H.B. No. 83H-6132, 1983).

Without addressing the question of enforceability of surrogacy contracts, an amendment to an Arkansas artificial insemination statute explicitly contemplates surrogate arrangements, and at least with respect to unmarried women allows an exception to the presumption that the childbearing mother is the legal mother of a child. It states that in the case of surrogate motherhood, the child "shall be that of the woman intended to be the mother." The statute does not address questions of evidence, such as the kind of agreement necessary to demonstrate who was intended to be the mother, or the enforceability of these arrangements. Nevertheless, it is the first statute in the United States of its kind. A Wisconsin bill calling for a presumption that the intended social parents are in fact more fit to raise the child also exemplifies the private ordering approach, but with some protection for the vulnerable child. Further, the bill attempts to ensure that if all the adult parties refuse custody, an adoptive home for the child would be found.

Consistent with the private ordering approach are State law provisions to ensure informed and voluntary consent by all parties. A number of bills require that the surrogate and the intended rearing parents be represented by attorneys, many further specifying that the parties be represented by separate counsel. Bills in at least five States require that the intended rearing parents review the results of medical, psychological, and genetic examinations of the surrogate mother before agreeing to hire her. Bills in Michigan and the District of Columbia propose that at least 30 days pass between the time that the contract is signed and the first insemination, to allow a cooling-off period (4). It is unclear if such provisions could meet all the objections of the New Jersey Supreme Court (see ch. 12), but the *Baby M* decision did say that State legislatures could legalize and regulate surrogacy, within constitutional limits (30).

The private ordering approach can be inadequate if parties fail to agree to a contract that spells out all contingencies and their outcomes. For example, a contract might fail to specify a remedy if one or both of the intended social parents were to die, leaving it unclear whether the surrogate mother or the State is responsible for the child. Contracts may also fail to specify the medical tests to be performed during pregnancy, remedies for failure to abide by lifestyle restrictions, or the lines of authority for emergency medical decisions concerning the health of the newborn. In the absence of State guidelines that create presumptive responses to these situations, private contracts may lead to disagreement and confusion. Courts attempting to enforce the contracts and carry out the parties' intentions could find it necessary to decide on matters not explicitly contemplated under the contract, making even these arrangements unclear as to their outcome and highly variable from State to State.

The Inducement Approach

The inducement approach offers individuals an exchange. By agreeing to follow prescribed practices—such as judicial review of the contract, adherence to a model set of terms and conditions, or use of a licensed surrogate matching service—the State facilitates legal recognition of a child born by the arrangement (14). For example, a Missouri bill introduced in 1987 would require that judges approve surrogate contracts before insemination takes place. In exchange, the bill would automatically terminate the rights of the surrogate mother, thereby offering the intended rearing parents the certainty that they will be able to gain custody of the child. The penalty for failure to follow these practices might be that the contract is unenforceable under State law or that adoption proceedings are ineligible for expedited treatment. Of course, penalties that harm a baby's psychological, physical, or even legal well-being would probably be unacceptable. A preliminary draft by the National Conference of Commissioners on Uniform State Laws takes a similar approach (60).

Another form of this approach is to induce use of a particular approved procedure or agency by offering some Government assurance of its quality. Thus, for example, Government could license particular adoption agencies to operate as surrogate matching services. As a condition of licensing, the agency could agree to certain conditions, such as use of a standard contract or psychological screening of participants. The State would also ensure that the personnel of the agency meet certain minimum criteria, such as years in practice or professional training. Although there would be no penalty for failure to use the service, many participants would likely be interested in assuring themselves that the surrogates they hire have been screened for drug or alcohol abuse, that the persons for whom they bear children have been interviewed to identify the kind of home they plan to provide for the child, or that the contract they sign has been reviewed for fairness, completeness, and enforceability.

Any inducement approach that relies at least partly upon licensing surrogate matching agencies permits the Government to prevent abuses without necessarily limiting the freedom of individuals who wish to pursue these agreements. For example, licensing could specify permissible and impermissible ways of recruiting surrogates and infertile couples, standardize the medical testing and screening of the participants and their gametes, require monitoring of the health of the baby, or set standard fees and expenses. To broaden access to the poor, licensing could provide sliding fee scales and agency-financing.

Inducement or regulatory approaches may also, however, enable the Government to specify who will be permitted to take advantage of the agencies. Thus, for example, agencies might be limited to serving married couples, thereby leaving unmarried couples, homosexual couples, and single persons without access to the advantageous, State-approved method of surrogate adoption. Any such limitations would be subject to constitutional review, particularly to the extent that they are viewed as State interference in the right to privacy with regard to procreative decisions (see ch. 12).

The Regulatory Approach

State regulation can also be used to create an exclusive mechanism by which an activity may be carried out. A number of proposals have been made to regulate surrogacy. Bills in Florida, Illinois, New Jersey, and South Carolina, for example, would permit only married couples to hire a surrogate, and bills in at least eight States would further specify that surrogates might be used only for medical reasons, such as inability to conceive or to carry a pregnancy to term (4). A South Carolina bill would require extensive investigation of intended rearing parents' homes, as is generally done prior to adoption. Bills also propose standards for potential surrogate mothers, for example excluding women who have never had children before.

Besides regulating who may participate in surrogacy arrangements, a number of bills specify that the surrogate and at times the intended rearing parents undergo psychological screening or counseling, and some bills would require the biological mother and father to undergo testing for sexually transmitted diseases. This latter point takes on particular importance after the report that one surrogate was not stringently screened before she became pregnant, resulting in a child born seropositive for the human immunodeficiency virus, and rejected by the biological father and his wife (20). Regulations have also been proposed in South Carolina to require the surrogate mother to follow physician orders during pregnancy, to adhere to a particular prenatal care schedule, and to forgo abortion unless medically indicated.

Regulations have also been proposed to limit compensation to the surrogate mother, or to set forth pro rata schedules of fees in the event of abortion, miscarriage, or stillbirth. Some proposals have also been made to maintain State records of surrogacy arrangements, and in a few cases, to provide the child, at age 18, with information about his or her conception. State proposals have split on whether to allow the surrogate a period after birth in which to change her mind about relinquishing custody, and whether the remedy should she do so would be monetary damages or specific enforcement of the contract's custody provisions (4,36).

The Punitive Approach

The punitive approach imposes sanctions upon certain specified practices, prohibits commercialization of the surrogacy arrangement, or denies enforceability to surrogate contracts. Thus, for example, a bill could prohibit payment of fees to surrogates, by stating that commercial surrogacy contracts are void and therefore unenforceable. This was the approach taken in the 1987 Louisiana law. Proposals in Alabama, Minnesota, Nebraska, and New York take this same approach, while proposals in Connecticut, Illinois, North Carolina, and Rhode Island would void even noncommercial contracts. Voiding these contracts means that should the surrogate change her mind about relinquishing the child, she will stand on at least equal footing with the genetic father when she seeks permanent custody. In some States, if she is married, her husband will be presumed by law to be the child's father (see ch. 13), leaving the genetic father with a difficult task should he seek custody of the baby.

Punitive measures may be directed at a variety of parties. Civil and criminal sanctions could attach to the professional matching services, to the physicians and attorneys who are involved in the arrangements, or to the surrogates or couples themselves (14). Nevada's legislature, for example, is to consider a bill making surrogate matching a felony punishable by up to 6 years in prison. A Michigan bill also makes surrogate matching a felony, with stiff penalties for any person who matches a couple to a surrogate who is not of legal age. The bill would make the participation by the surrogate and the genetic father a felony as well. However, the fact that surrogacy does not always require the services of a physician or an attorney, and therefore is not easy to detect, means that punitive approaches are unlikely to completely eliminate surrogate arrangements, although they may drive them underground.

SUMMARY AND CONCLUSIONS

The legal status of surrogate arrangements is still unclear. Despite activity in over half the State legislatures, only Arkansas, Kansas, Louisiana, and Nevada have enacted legislation either facilitating or inhibiting the arrangement. Louisiana has voided commercial surrogacy contracts, while Arkansas has begun to regularize the legal parentage of the child. Nevada has exempted surrogacy contracts from its baby-selling prohibition, and Kansas, from its prohibition on adoption agency advertising.

State court decisions are similarly sparse, but consistently find surrogacy contracts unenforceable in the event of a custody dispute, although the decisions do split on whether the contracts necessarily violate State adoption law. The 1988 *Baby M* case held that commercial surrogacy contracts are completely void and possibly criminal. This decision, coming from the highest court in New Jersey, may well be influential in other State courts. Nevertheless, absent Federal legislation or a Federal judicial decision identifying constitutional limitations on State regulation in this field, State courts and legislators are likely to continue to come to different conclusions about whether these arrangements can or should be enforced, regulated, or banned.

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Chapter 15

Frontiers of Reproductive Technology

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Chapter 15

Frontiers of Reproductive Technology

The field of reproductive endocrinology began to blossom in the 1930s with the description of reciprocal hormonal control of the ovaries and testes by the pituitary gland. Soon after, at the close of World War II, the modern era of biomedical research began. Inspired by Federal funding through the National Institutes of Health (NIH), rapid advances were recorded in the United States in broad areas of biology and medicine, including reproduction.

In the 1960s, the technique of radioimmunoassay enabled measurement of minute amounts of reproductive hormones and permitted characterization of both normal reproductive health and pathology. In the 1960s and 1970s, synergism between contraceptive research and fertility research led to identification and purification of numerous natural and synthetic reproductive hormones. This era also saw an increased research effort on mammalian eggs and early embryos that was facilitated by advances in nonhuman in vitro fertilization (IVF) and preimplantation development. Beginning in the 1970s, advances in microsurgery, fiber optics, and ultrasound—allowing for the first time routine visualization and retrieval of eggs—propelled novel reproductive technologies into clinical practice.

Today, advances in infertility prevention and treatment depend heavily on reproductive research in both humans and animals. Large domestic animal species such as cattle and pigs, because of their economic importance, play a particularly prominent role in reproductive research. Several methods of assisted reproduction are, in fact, better developed in animals than in humans. The frequency and success of embryo freezing, for example, have soared in the 1980s as the basis for a large commercial industry developed for improved breeding of cattle. The use of IVF, on the other hand, is most well developed in humans.

This chapter reviews the state of the art in selected areas of reproductive technology and, where possible, projects potential developments over the next decade. Humans have made great strides in understanding reproduction (for a historical perspective, see box 15-A), but a great deal of human reproduction remains a profound mystery.

The developments in reproductive technology discussed in this chapter have been accompanied by an emerging literature in the social sciences. Through the next decade, researchers are likely to report with increasing frequency on the positive and negative impacts of reproductive and allied technologies on the behavior of individuals and society as a whole.

IN VITRO FERTILIZATION

Ten years have passed since the birth of baby Louise Brown, the first human to be conceived by IVF. Some 5,000 IVF babies worldwide have been born since. If the prevailing rate of successful pregnancies (i.e., pregnancies resulting in live births) at today's most expert clinics—about 15 to 20 percent per case in which embryos are transferred—is ultimately achieved at other clinics, some 6,000 successful IVF pregnancies per year may take place by the turn of the century. (One recent estimate assumes that 220 active IVF programs worldwide will undertake 30,000 IVF treatment cycles annually by then. Each treatment cycle involves the attempted insemination of five oocytes, for a total of 150,000 oocytes per year. Twenty percent of the 30,000 cycles are assumed to result in successful term pregnancies, including some multiple births (22).) This means that IVF would account for fewer than 1 percent of the babies born each year in the United States.

Since the first report of pregnancy following IVF (12), the methods of human IVF and embryo culture have to a large extent been simplified and standardized, although there is no universally accepted set of techniques. One index of the research

Box 15-A.—A Look Back

From ancient times until the early 1600s, the view persisted that babies were conceived by mixing menstrual and seminal fluids. Aristotle maintained 2,300 years ago that development begins when the male provides the active form to the passive female substance. In 1651, William Harvey raised the fundamentally different claim that all animals are derived from an ovum, with the innate capacity to develop being influenced by the male semen. The discovery by Reinier de Graaf that follicles within the "female testes" were released prior to the appearance of embryos within the uterus gave credence to this belief, although the actual origin and nature of an egg remained obscure.

Despite the discovery of sperm by Anton van Leeuwenhoek in the 1670s, the view prevailed that all organisms arise from eggs that require the stimulating effects of male semen to develop. Most naturalists of the 1700s believed sperm to be parasites of the testis with no function in fertilization. With the introduction of cell theory in the mid-1800s, sperm changed from being seen as parasitic organisms to cells necessary for fertilization. Only some 135 years ago—in the 1850s—was it resolved whether sperm played no role in fertilization, kept the seminal fluid in circulation, activated the egg by mere contact, or actually penetrated the egg. By then, fertilization was believed to involve the penetration and dissolution of the sperm within the egg, thus providing a basis for belief in inheritance.

The manufacture of microscope lenses free from chromatic and spherical aberration in the late 1800s and the refinement of fixing, staining, and sectioning techniques led to extensive investigations into cell and nuclear division. The discovery at that time of cell nuclei and chromosomes generated a further controversy, not resolved until the early 1900s, between those who argued that fertilization involved a complete fusion of male and female nuclear material and those who denied this. To the former, fertilization was a conservative blending process, while to the latter it led to variations in offspring. Recognition of meiosis and chromosomal recombination in the formation of sperm and egg cells resolved this debate.

SOURCE: Adapted from W.F. Bynum, E.J. Browne, and R. Porter, *Dictionary of the History of Science* (Princeton, NJ: Princeton University Press, 1981).

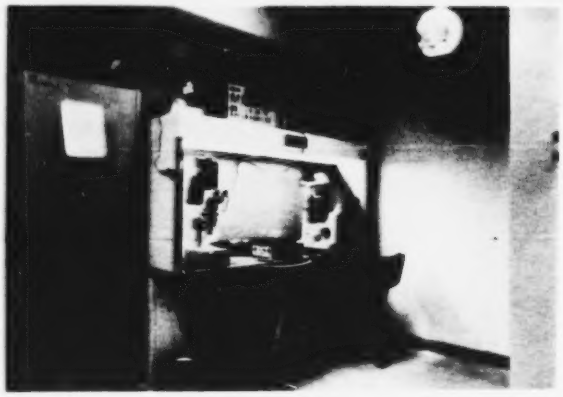

Photo credit: Martin Quigley

In vitro fertilization laboratory setup

activity in this area is the rapid growth of the biomedical literature on IVF and embryo transfer—from only 8 papers in 1980 to over 300 in 1986 (11). The laboratory techniques of IVF and embryo culture no longer represent the major weak point of noncoital reproduction, as repeatable techniques move from program to program (29). The principal determinant of the success of IVF today may well lie in the physiological state and developmental competence of sperm and eggs used in the procedure (38). An additional determinant is synchronization of the cultured, cleaving embryos with receptivity of the uterine endometrium, and transfer at the optimum time. Important scientific information concerning this uterine "window of receptivity" is now becoming available (33).

Indications for IVF have broadened and will likely continue to broaden beyond couples with untreatable, tubal-factor infertility to include couples with endometriosis or with cervical factor, male factor, or unexplained infertility—and essentially all infertile couples with whom conventional infertility therapy (see ch. 7) has been used unsuccessfully or for whom there is no other therapy available. As IVF is used in an increasing number of circumstances that do not positively preclude natural conception, conceptions that are actually independent of treatment can be expected in these programs (20,31). Such treatment-independent pregnancies will overstate the apparent success rate of IVF, although to what degree is uncertain.

The most comprehensive data on IVF success rates in the United States come from 41 clinics that treated 3,055 different patients in 1986 (28). The clinics performed 4,867 stimulation cycles, or 1.6 cycles per patient; the outcomes of these cycles are listed in table 15-1. Some 59 percent (2,864) of the stimulation cycles were followed by embryo transfer. The median number of embryos transferred was three.

Embryo transfer led to clinical pregnancies—i.e., a positive fetal heart documented by ultrasound—in 485 cases, or 17 percent of the time. The 485 clinical pregnancies led to 311 live births, an unreported fraction of which were multiple births. Thus, embryo transfer led to a live birth less than 11 percent of the time. Put another way, about 6 percent of the initial stimulation cycles resulted in a live birth (28).

At the most expert IVF programs, success rates exceed the average. One program that treated 650 different patients from 1983 through 1987 is profiled in table 15-2. The program performed 723 oocyte recovery procedures that led to 662 embryo transfer cycles. The average number of embryos transferred was four (35).

Embryo transfer led to confirmed pregnancies—i.e., either a gestational sac confirmed by ultrasound or the products of conception identified by pathologic specimen—in 208 cases, or 31 percent of the time. The 208 clinical pregnancies led to 103 live births, an unreported fraction of which were multiple births. Thus, embryo transfer led to a live birth about 15 percent of the time. Put another way, about 14 percent of the oocyte recovery procedures (and a smaller percentage of the initial stimulation cycles) resulted in a live birth (35).

Table 15-1.—In Vitro Fertilization in the United States, 1986[a]

Outcome	Number
Patients seen	3,055
Stimulation cycles	4,867
Embryo transfer cycles	2,864
Embryos transferred per cycle (median)	3
Clinical pregnancies[b]	485
Ectopic pregnancies	22
Miscarriages or stillbirths	156
Live births[c]	311

[a] Retrospective data reported voluntarily by 41 U.S. clinics.

[b] Positive fetal heart documented by ultrasound.

[c] Includes an unreported number of multiple births.

SOURCE: Medical Research International and the American Fertility Society Special Interest Group, "In Vitro Fertilization/Embryo Transfer in the United States: 1985 and 1986 Results From the National IVF/ET Registry," *Fertility and Sterility* 49:212-215, 1988.

Table 15-2.—Statistical Profile of an Expert In Vitro Fertilization Program, 1983-87[a]

Outcome	Number
Patients seen[b]	650
Stimulation cycles	(not reported)
Oocyte recovery procedures	723
Oocytes recovered	3,759
Oocytes recovered per procedure (mean)	5
Embryo transfer cycles	662
Embryos transferred per cycle (mean)	4
Confirmed pregnancies[c]	208
Live births[d]	103

[a] Data reported by the three facilities of National Fertility Institute, Inc. (Northern Nevada Fertility Center, Reno, NV, Pacific Fertility Center, San Francisco, CA; Pacific IVF Institute, Honolulu, HI).

[b] All women were under age 40; primary diagnoses were tubal disease (65 percent), male factor infertility (19 percent), and unexplained infertility (16 percent).

[c] Gestational sac confirmed by ultrasound or products of conception confirmed by pathologic specimen.

[d] Includes an unreported number of multiple births.

SOURCE: G. Sher, Director, Pacific Fertility Center, San Francisco, CA, personal communication, Jan. 25, 1988.

It may be difficult for the most expert IVF programs to sustain their success rates as their good reputations attract patients with the most difficult cases of infertility (e.g., unexplained infertility). Similarly, an increase in the average age of patients would likely trim an IVF program's success rates. Information about a clinic's patient mix is crucial to interpreting its success rates (see ch. 9).

IVF programs can serve as a source of biological materials, providing an opportunity for experimentation that adheres to legal and ethical principles and that yields valuable information about human fertilization. Table 15-3 gives an overview of components of the IVF procedure whose examination, correlated retrospectively with the outcome of a given case of IVF, could yield relevant information for human fertility research (38).

An offshoot of research surrounding IVF is likely to be, paradoxically, progress in contraceptive development. Contraceptive methods that precisely block the interaction between sperm and egg—thus preventing fertilization without systemic effects on the body as a whole—have long been sought by reproductive scientists (42). By bringing sperm and egg together under laboratory scrutiny, IVF provides this research opportunity (22).

Table 15-3.—Sources of IVF Byproducts and Some Possible Uses in Research

Source of IVF byproduct	Research use
Sperm sampling	Examination of sperm (membranes, enzymes, bound antibodies, effects of illness, studies of normal development)
	Analyses of seminal plasma (chemical composition, proteins, sperm antibodies, function of seminal vesicles, prostate function, screening for prostate cancer)
Recovery of oocyte/cumulus cells	Analyses of follicular fluid (hormones, proteins, sperm antibodies)
Sperm washing and preincubation	Examination of preincubated sperm (membranes, enzymes, bound antibodies, character of motility, fertilizing capacity)
Change of media after in vitro insemination	Analyses of spent insemination media (secretions of cells that surround the oocyte: steroids, peptides, proteins, biological effects)
	Examination of cultured cumulus cells (ultrastructure, steroid-producing enzymes, other proteins)
	Examination of supernumerary sperm
Embryo transfer	Examination of eggs that failed to cleave (ultrastructure, chromosomes, zona antibodies, interaction of sperm with zona pellucida)
	Analyses of spent growth media (steroids, proteins of embryonic origin)
Monitoring of pregnancy	Examination of spontaneously aborted conceptuses (chromosomes)

SOURCE: Adapted from J. Tesarik, "From the Cellular to the Molecular Dimension: The Actual Challenge for Human Fertilization Research," *Gamete Research* 13:47-89, 1986.

Despite the widespread practice of IVF in the United States, there is today a de facto moratorium on Federal funding of any research involving in vitro fertilization of human sperm and egg, fertilized ova, or early embryos. Research that involves in vitro fertilization of human sperm and eggs is in effect excluded from Federal support because of the absence since 1980 of an Ethics Advisory Board within the Department of Health and Human Services (DHHS); such a board is required to advise the Secretary as to the ethical acceptability of such research (45 CFR 46.204(d)).

Within DHHS, research funding for human IVF is under the jurisdiction of the Center for Population Research of NIH. Although the Center's Reproductive Sciences Branch (with a fiscal year 1987 budget of $83.1 million) supports research on, for example, sperm maturation and follicular hormone production, it does not support research that involves fertilizing human eggs with human sperm unless that research is directly related to IVF carried out as a part of an infertile couple's routine clinical care.

The Center reports receipt of 10 grant applications related to human IVF between 1980 and 1987. One proposal, for example, involved injection of human sperm into human ova in an attempt to overcome infertility that was thought to be due to sperm antibodies in the female. Three others proposed to correlate sperm characteristics (e.g., motility) with successful pregnancies. Seven of the ten grant applications were approved on scientific merit; but did not rank high enough to be funded. In failing to achieve a fundable ranking, these applications were not candidates for the next step, ethical review. Thus, from 1980 to 1987, no grant application involving human IVF actually made it to the point where review by the Ethics Advisory Board was required (21).

This blanket statement is misleading, however. Investigators indicate that they *do not submit* proposals involving in vitro fertilization of human egg and sperm because of a widespread awareness of the de facto ban on such research. The dimensions of this chilling effect of the moratorium on IVF research are such that NIH estimates it might receive more than 100 grant applications related to human IVF if the Ethics Advisory Board were extant (21). At the moment, funding for research on human IVF comes from the private sector, including pharmaceutical companies and IVF patients, through their fees, and from university and medical center operating budgets.

GAMETE INTRAFALLOPIAN TRANSFER

Since the first description of gamete intrafallopian transfer (GIFT) in 1984 (6), numerous reports have appeared confirming its utility in treating some types of infertility. One report combining data from clinics in nine countries ranked the chief diagnoses among GIFT patients as unexplained infertility, endometriosis, and male factor infertility (see table 15-4). Overall, 29 percent of the stimulation cycles resulted in clinical pregnancies established by GIFT, making it biologically competitive with, if not superior to, IVF.

Table 15-4 indicates a broad range of effectiveness of GIFT, depending on the factors contributing to a couple's infertility. Success in achieving a clinical pregnancy by means of GIFT ranged from only 10 percent among couples with immunologically based infertility to a peak of 56 percent success among women with premature ovarian failure. It is important to note that as many as one in three clinical pregnancies fails to go to term.

It is unlikely, however, that gamete intrafallopian transfer will replace IVF. In most cases of damage to the oviducts, for example, GIFT is not an option (because the gametes need to be placed into the oviduct), whereas IVF is possible (because fertilized ova are placed in the uterus, bypassing damaged oviducts). Yet in the years ahead gamete intrafallopian transfer will likely become an increasingly popular option for cases of chronic unexplained infertility, for some cases of endometriosis, for cases where artificial insemination by donor has failed, for infertility due to cervical factors, for men with various seminal deficits, and for women with premature ovarian failure.

Proficiency with gamete intrafallopian transfer is rapidly spreading among clinicians, and there is no apparent technical barrier to it being offered by most units that deal with reproductive medicine and treatment for infertility. Unlike IVF, no requirement exists for expertise in, or a facility for handling, embryo culture. On the other hand, a clinical drawback to GIFT is that—if no pregnancy ensues—the procedure provides no diagnostic information about the fertilizability of the female's oocytes by the male's sperm. Defects in

Table 15-4.—Clinical Pregnancies Following GIFT[a]

Etiology	Number of stimulation cycles	Number of clinical pregnancies	Success rate[b] (percent)
Unexplained infertility	796	247	31
Endometriosis	413	132	32
Male factor	397	61	15
Tubo-peritoneal	210	61	29
Failed artificial insemination by donor ..	160	66	41
Cervical	68	19	28
Immunological	30	5	10
Premature ovarian failure ..	18	10	56
Total	2,092	601	29

[a] Results of a multinational cooperative study.

[b] Percent of stimulation cycles leading to a clinical pregnancy. As many as one in three such clinical pregnancies fails to go to term.

SOURCE: R.H. Asch, UCI/AMI Center for Reproductive Health, Garden Grove, CA, personal communication, December 1987.

the fertilizing ability of sperm or oocytes that might have been identified during IVF can go unnoticed with gamete intrafallopian transfer, when gametes are placed in the oviduct. An additional drawback is that, unlike IVF, gamete intrafallopian transfer usually requires the woman to undergo general anesthesia.

UTERINE LAVAGE TO RETRIEVE A FERTILIZED OVUM

Since 1983, about a dozen viable pregnancies have been reported as a result of flushing a preimplantation embryo (a fertilized ovum) from the uterus of a fertile donor and transferring it to an infertile recipient (8,9,16). This procedure initially seemed promising, particularly for infertile recipients without ovaries or with premature ovarian failure.

The future of this technique is uncertain (37). First, the success of IVF and gamete intrafallopian transfer, using multiple donor eggs, in treating women with premature ovarian failure exceeds that of fertilized ovum transfer where, to date, only one fertilized ovum at a time is transferred. Also, it remains to be shown that safe supranormal stimulation of the ovaries of ovum donors is possible in the ovum transfer technique.

Second, active IVF or gamete intrafallopian transfer programs, with sufficient patient populations providing an abundance of extra donor eggs and with a ready number of hormonally receptive recipients, can more easily arrange for donation of unused eggs. With increasing success in freezing eggs in years down the road, however, IVF and gamete intrafallopian transfer patients who now donate may become reluctant to do so when they themselves could receive the same eggs at a later date. At the same time, efficient freezing would eliminate the need to synchronize donor with recipient in the lavage procedure.

Third, certain risks to the fertile donor, such as ectopic pregnancy, multiple pregnancy as a consequence of supranormal stimulation of ovulation, and transmission of disease (e.g., acquired immunodeficiency syndrome) via semen, may render this technique impractical if not reduced to negligible levels. Such risks may be unacceptable for some in light of the suitability and success rates of IVF and GIFT.

FREEZING EMBRYOS

Embryo freezing is an attractive adjunct to IVF to conserve embryos, obviate the need for repeat egg retrieval procedures, and reduce the risk of multiple pregnancy when several embryos (i.e., more than three or four) are available for transfer. In Australia and Europe, about 60 children have been born from the transfer of thawed embryos; the first such U.S. birth occurred in 1986. Two dozen or more IVF programs in the United States have stored frozen embryos, but the technique is still experimental and requires additional research to improve success.

Initial research in France suggests that three factors influence human embryo survival after thawing: the developmental stage of the frozen embryos, the appearance of the embryo at the time of freezing, and the mode of ovarian stimulation in the IVF cycle (39). In the French study, optimal success was obtained by using programmed hormonal stimulation and selecting for 1-cell embryos or 2- and 4-cell embryos with a favorable appearance. There was also a tendency for better pregnancy rates if embryo storage did not exceed 1 to 2 months.

Research with cryopreserved animal embryos suggests that embryos frozen and stored in liquid nitrogen at −196 °C remain viable for 10 years or more, similar to cryopreserved sperm. Embryo freezing technology is especially well developed for laboratory mice and cattle; in farm animals (cattle, sheep, goats, and horses) as a group, the expected pregnancy rates from frozen-thawed embryos range from 35 to 55 percent (18). The farm animal embryos that exhibit the best viability following freezing are those frozen at the morula or blastocyst stage of development, well beyond the stage (i.e., 1 to 8 cells) at which most human embryos have been frozen to date.

FREEZING EGGS

Three births have been recorded in Australia and West Germany from eggs that were frozen and thawed. The routine capability to freeze and store eggs, in much the same manner that sperm are frozen for later use, would obviate much of the need to freeze embryos, thereby reducing the ethical and legal dilemmas inherent in the cryopreservation of human embryos (see chs. 11 and 13). An egg's chromosomes, however, are less hardy than a sperm's (which are highly condensed), and their fragility may make them intolerant of the rigors of freezing and thawing. The possibility of developmental anomalies arising in offspring conceived from frozen eggs—a major unanswered question—is cited as justification for chromosomal analysis of such embryos before attempting transfer of other such embryos for pregnancy. As with several of the technologies discussed in this chapter, this raises the issue of embryo use for research rather than pregnancy (22).

The most pressing clinical applications for freezing eggs arise in situations where women face the loss of fertility due to pelvic disease, surgery, or imminent radiation or chemotherapy for ovarian cancer or other malignancies. Patients could have one or more cycles of ovarian hyperstimulation so that oocytes could be collected and stored prior to the fertility-threatening treatment (26).

Oocyte freezing and thawing is technically more difficult and costly than embryo freezing and thawing. First, unlike a multicellular embryo, an egg consists of a single cell surrounded by a single membrane, damage to which kills the egg. Second, eggs must be frozen soon after retrieval, on a daily basis in a laboratory, whereas embryos can be maintained in culture and frozen in batches every other day or so. Third, in order to ultimately obtain a sufficient number of fertilized embryos, extra eggs must be frozen and thawed to account for the failure of some eggs to fertilize. For the latter reason, cryopreservation of eggs would have to be more successful than cryopreservation of embryos in order to be competitive. Therefore, in the near term, egg freezing is unlikely to surpass embryo freezing (40,41). With improved technology (2), however, and if chromosomal damage is not a factor, egg freezing could take its place alongside cryopreservation of sperm in the mainstream of reproductive technology.

MICROMANIPULATION OF SPERM INTO OVA

In animals, the microscopic surgical placement of a single sperm into an egg can achieve fertilization and trigger cleavage, but there has been little success in triggering embryonic development and producing offspring. Establishing such a treatment for humans would permit infertile men who either produce a reduced number of sperm (severe oligospermia), produce ejaculates with a large percentage of abnormal sperm, or produce sperm that are unable to fertilize their wives' ova to attempt fertilization by means of IVF by sperm micromanipulation (22,34). The ability to inject sperm cells could also be useful in conjunction with a reliable technique for separating X- and Y-bearing sperm (discussed in next section), if that technique had a low yield of viable sperm (15).

One type of micromanipulation of sperm involves insertion of a sperm under the egg's outer membrane, the zona pellucida, by using a fine glass needle that mechanically breaches the membrane. Successful fertilization of a human oocyte (but not embryonic development) was reported with this technique in Australia in 1987 (24). Another type of micromanipulation, called "zona drilling," involves chemically etching the egg's outer membrane to create an opening for sperm penetration. The egg is anchored into place on a dish and

Photo credit: Martin Quigley

Zona drilling

a needle is used to introduce a single sperm, which may then fertilize the egg (19).

Micromanipulation of sperm into ova in humans appears valuable as an adjunct to IVF, and successful human and domestic animal pregnancies may be recorded before the next decade is out. This technique is of potentially great value for treating male factor infertility, most of which is due to unexplained oligospermia. The technique carries the risk, at least in theory, of fertilizing an egg with a sperm that otherwise would have been unable to fertilize the egg, with unknown developmental consequences.

Micromanipulation of a different sort also lies on the visible horizon—i.e., the multiplication of genetically identical individuals through cloning. Initial research in sheep and cattle indicates that nuclei from multicellular embryos can be injected into unfertilized, enucleated eggs and produce offspring of the same genotype (18,47). The research necessary to develop such a technique in humans is unlikely to soon be deemed ethically acceptable in the United States for several reasons, not the least of which is concern about deliberately creating genetically identical humans.

SEXING SPERM CELLS

The only established difference between female (X-bearing) sperm and male (Y-bearing) sperm is DNA mass, with Y-bearing sperm being about 3 percent lighter in weight than X-bearing sperm. Many articles have appeared in the scientific literature on attempts to separate X- and Y-bearing sperm. Most studies have been conducted on the semen of laboratory animals, most often rabbits. Methods evaluated over the years (1) include separation by mass, electric charge, or staining, and sperm migration through cervical fluids. Other methods focus on manipulation of vaginal chemistry by diet or douching in order to select sperm. Although individual experiments using some of these approaches have been encouraging, usually the results could not be replicated.

The most recent approach to sexing human sperm cells involves the use of a protein solution, bovine serum albumin, to separate X- and Y-bearing sperm (13). According to the theory behind this procedure, Y-bearing sperm migrate preferentially into the protein solution and can then be washed and used for artificial insemination in an attempt to conceive a male. This method is protected by patents in the United States and abroad and has been used by some 50 clinics worldwide to produce about 400 babies. Although it is reported to tip the sex balance of offspring from the norm of just over 50 percent males to as high as 75 percent males, some members of the scientific community remain skeptical of even this degree of success attributed to semen sexing technology. In 1986, the American Fertility Society stated that current techniques for separating X- and Y-bearing sperm are not adequate to provide reasonable assurance of success (3).

Selection for X-bearing sperm has been attempted with at least two methods. In one, X-bearing sperm are separated from Y-bearing sperm using solutions with different densities (23). In another, sperm are flushed through columns that preferentially retain Y-bearing sperm because of their smaller size. The X-bearing sperm flow through the column and can be used for insemination. Too few births have been reported to date to adequately evaluate this technique for producing females.

It is noteworthy that the ability to sex semen of farm animals and influence the sex ratio of animal progeny would be of great economic benefit to commercial livestock producers. A male calf of a dairy cow may be worth only $50, for example, while a female calf may be worth 10 times as much. The strong economic incentive in the livestock industry for sex selection—as well as human interest in selecting the sex of children, in some cases to avoid sex-linked genetic diseases—will continue to drive research in sexing of sperm for the foreseeable future.

In humans, there is likely an upper limit to the popularity of sex selection by separation of X- and Y-bearing sperm, should a reliable method become available. The process requires artificial insemination of the woman once the sperm are separated, and the overwhelming majority of couples are likely to prefer intercourse. Thus, the intrusive nature of artificial insemination will probably limit the broad use of sex selection, regardless of how reliable the selection of X- and Y-bearing sperm becomes in the future.

SEXING EMBRYOS

Although sexing the human fetus by evaluating chromosomal spreads in embryonic cells (collected by chorionic villi sampling or amniocentesis) is a well-established clinical procedure, sexing human embryos by such karyotyping has only recently been considered. Applying this procedure involves doing a biopsy of the embryo to examine the sex chromosomes of one cell. Such karyotyping has been reported in mice and cattle, but this method is unlikely to be developed for use in humans unless there is a general acceptance of human embryo biopsy. In such a case, embryonic cells would be evaluated from the biopsied part of the embryo, and the embryo would be made ready for transfer (18).

Researchers in the United Kingdom have demonstrated the identification of human male embryos using a commercially available DNA probe for Y-chromosomal DNA (46). The embryos, created solely for research purposes, were at the 2-cell through blastocyst stages. The DNA probe was applied to whole embryos, not samples of cells; it left the embryos unviable and the process took 4 to 8 days. Sexing embryos by this method will ultimately require embryo splitting and, because of the time required for the process, embryo freezing with later transfer. This is likely to become technically feasible, but will remain a laboratory technique without popular application for the foreseeable future. Basic studies of nonhuman preimplantation embryos may provide new approaches to embryo sexing.

GENETIC SCREENING OF GAMETE DONORS

It is impossible to exclude all sperm or egg donors capable of transmitting genetic disorders. Indeed, most couples conceiving a genetically abnormal child through intercourse show no characteristic that distinguishes them from couples having genetically normal children. In fact, the more severe an autosomal dominant trait, the greater the likelihood that the trait will have arisen in an affected individual as a result of a new mutation—i.e., one arising in the egg or sperm responsible for fertilization. Likewise, there is usually no recorded history of exposure to deleterious agents, nor are there consistently identifiable socioeconomic factors. The same can be expected for IVF, gamete intrafallopian transfer, and artificial insemination (37). In practice, relatively few prospective donors are excluded for genetic reasons (45).

Despite these limitations, some genetic screening is possible. A goal of excluding donors likely to place a pregnancy at greater risk than the rate of seriously anomalous offspring expected for the general population—about 3 percent—has been called realistic (36). No uniform criteria for such screening exist, but various guidelines have been suggested. Some methods include lengthy and often unwieldly donor screening forms for physicians to use while eliciting a complete history and conducting a physical examination.

Guidelines proposed in 1986 by the American Fertility Society (4) recommend that sperm donors: have no malformations, have no nontrivial Mendelian disorder, have no adult-onset disease with a genetic component (e.g., hypertension or epilepsy), not be a heterozygote for an autosomal recessive gene known to be prevalent in the donor's ethnic group for which heterozygosity can be determined, have no chromosomal rearrangement, be young, and have an Rh type compatible with that of the prospective mother. Similar exclusions pertain to egg donors.

In addition, first-degree relatives (i.e., parents and offspring) of male and female gamete donors should not have any nontrivial anomalies, autosomal dominant disorders of reduced penetrance or late age of onset, or autosomal recessive disorders of a high frequency in the population. For prospective female donors, those with heterozygosity for an X-linked recessive disease are also excluded.

The practical impact and uniform application of these guidelines are today unknown. OTA surveyed practitioners of artificial insemination in the United States, asking—among other questions —if the practitioner uses professional society guidelines and, if so, which ones (43). The guidelines are certain to assume increasing importance with the continued practice of noncoital reproduction and as the capability to test for human genetic disorders grows.

In recent years, the powerful techniques of molecular biology have been used to locate genes or chromosomal loci responsible for several inherited diseases, such as Huntington's disease, Duchenne's muscular dystrophy, familial Alzheimer's disease, autosomal dominant manic-depressive disease, myotonic dystrophy, and familial amyloidotic polyneuropathy. Likely to be located in the near future are genetic loci for neurofibromatosis, familial spastic paraparesis, and torsion dystonia. Further in the future lies the possibility of locating the gene for virtually any dominantly inherited disorder, provided that sufficiently large families with the disorder are available for analysis (27). With tests for a growing number of human genetic disorders likely to become available through the next decade, diagnostic testing of gamete donors for a handful of genetic diseases may become routine.

HEALTH OF INFANTS CONCEIVED BY IVF OR GIFT

Initial reports indicate that babies conceived in the laboratory through IVF face the same low risk of birth defects as babies conceived through intercourse. This finding comes from several studies, including one of 164 babies conceived between 1983 and 1985, half by IVF and half by normal means (48). A French study of 2,342 IVF pregnancies around the world found no significant increase in the rate of birth defects, once the data were corrected for the risks of increased maternal age and multiple pregnancies (10). Among 574 live births following IVF at 41 U.S. clinics in 1985 and 1986, 18 chromosomal abnormalities or congenital anomalies were recorded (3 percent) (28). In contrast, a study from North Carolina of 70 IVF pregnancies reports an excessively high 6 anomalies (30).

As with IVF, early indications are that gamete intrafallopian transfer confers no risk of excessive congenital abnormalities. The first 800 GIFT cases worldwide resulted in one chromosomal abnormality, a trisomy 21 (7).

Rigorous proof that neither IVF nor gamete intrafallopian transfer contributes to an increased prevalence of anomalies in offspring is today limited primarily by small numbers of potential subjects (37). For example, a sample size of 1,151 IVF pregnancies and 1,151 controls would be required to exclude (with 95 percent certainty) a threefold increase in chromosomal abnormalities that have an incidence of 0.5 percent. To detect a twofold increase, the required sample size would be 4,668 in each group. A sample size of 244 IVF pregnancies would be required to exclude a threefold increase in total congenital anomalies (3 percent incidence), whereas 748 would be necessary to detect a doubled increase.

The IVF or gamete intrafallopian transfer population is also less than ideal to study because of inherent limitations in sample characteristics. Pooling tabulated outcomes of IVF or gamete intrafallopian transfer pregnancies—although fashionable—is hazardous because groups of women achieving such pregnancies come from diverse geographic areas and countries, with possible exposure to a host of potentially deleterious agents. An even more important confounder is the varying history of infertility among pooled patients: idiopathic infertility, for example, may be related to (as yet undetectable) genetic abnormalities in sperm or eggs. Finally, criteria for anomaly assessment are not standardized.

MATERNAL HEALTH CONSEQUENCES OF IVF AND GIFT

Women undergoing IVF or other forms of noncoital reproduction are not comparable to the general population. Their pregnancy outcomes, therefore, are not likely to be comparable. Inability to have achieved pregnancy readily dictates that such couples are older than the childbearing population at large. As a result, they are expected to be at increased risk for a variety of age-related adverse perinatal outcomes (25). Older women naturally have had a longer time to manifest certain illnesses (e.g., chronic high blood pressure) that might not have been evident had they been able to achieve pregnancies earlier in life. Research will be needed to verify the present thinking that there is no apparent reason to suspect maternal complications in excess of those found in a comparable age group.

Adequate studies of maternal health consequences are today lacking, and there are at least two practical problems in conducting such research. First, the worldwide experience with IVF totals about 5,000 births; that of gamete intrafallopian transfer is about half that number, and fertilized ovum transfer far less. These numbers are too small for statistically rigorous studies. Second, IVF couples generally come from diverse geographic venues, even when treated at a given center. Successful pregnancies are usually delivered in a couple's local community, where outcomes are not monitored in a consistent fashion.

In the United States, one report of maternal consequences of IVF consists of 125 pregnancies conceived between 1981 and 1984 (5). These resulted in 100 deliveries, producing 115 babies. Only 12 deliveries actually happened at the IVF clinic (Norfolk, VA); 88 deliveries occurred elsewhere in the United States and in three foreign countries. The spontaneous clinical abortion rate (18.4 percent) was slightly higher than that of the general population, but similar to that of women undergoing ovulation induction. In 1986, 485 clinical pregnancies among 41 U.S. IVF clinics resulted in 151 miscarriages (31 percent) (28). Another study reports a spontaneous clinical abortion rate of 28 percent among women 40 years and older undergoing IVF (32).

A higher than normal rate of delivery by cesarean section—despite no indication of increased likelihood of fetal distress—has been noted among IVF pregnancies (5). The increased rate of cesarean section may be a consequence of high levels of anxiety generated in physician and patient alike by an IVF pregnancy. This leads to a tendency to take every medical precaution at delivery, a circumstance generally favoring cesarean rather than vaginal delivery.

When ovarian stimulation with human menopausal gonadotropin or clomiphene citrate is undertaken prior to IVF or gamete intrafallopian transfer, hyperstimulation can land the woman in the hospital. Among IVF clinics, this has been reported at the rate of 1.2 to 1.5 patients per 1,000 stimulation cycles (28).

PSYCHOLOGICAL EVALUATION OF PARTICIPANTS IN NONCOITAL REPRODUCTION

The circle of participants in reproduction today encompasses biological parents, legal parents, and immediate family members of participants (e.g., siblings of a child conceived through assisted reproduction technology). It also includes medical personnel who share responsibility for the successes and more numerous failures of the procedures, as well as those whose participation in assisted reproduction was rejected (e.g., unsuitable gamete donors or surrogate mothers). Each group of individuals is subjected to unique stimuli and can be expected to exhibit a range of psychological responses. Yet few participants have been systematically studied, and little is known about the psychology of participants in assisted reproduction.

The intended child is the principal participant in assisted reproduction and arguably the individual whose psychological status is of greatest concern. Three major psychological questions regarding the child are:

- What are the developmental sequelae, if any, of prenatal procedures such as in vitro embryo culture or embryo cryopreservation?
- In the case of surrogate motherhood, what is the child's relationship with his or her birth mother (even if the relationship occurs only in the child's fantasy life)?
- In the case of ovum donation or artificial insemination by donor, what is the child's relationship to his or her genetic parent(s) (again, even if this occurs only in the child's fantasy life)?

From the child's perspective, ovum donation or artificial insemination by donor may at times differ from adoption—with unknown psychological consequences to the child. Adoption, for example, can involve parents giving up a child for the child's own good. In contrast, gamete donation can involve parents giving up gametes with no knowledge of the child to be born and at times for the parent's financial reward.

The major research question regarding participants in assisted reproduction is the descriptive measurement of what happens to them psychologically from the first contact with infertility evaluation and treatment through the years that follow. This type of controlled, longitudinal research is essential. The National Institute of Child Health and Human Development is moving toward establishing a health surveillance system of women undergoing treatment for infertility with IVF (44). Similar systems would be useful for the children so conceived, the genetic (donor) parents and spouses, and spouses of those who underwent infertility treatment (who may themselves undergo treatment).

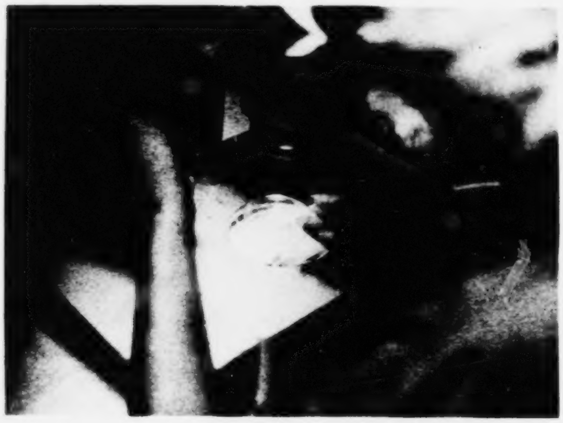

Photo credit: Martin Quigley

Identification of egg under microscope in IVF laboratory

Along with controlled, longitudinal research, studies are needed of the baseline psychological status of each group of participants. Such studies are necessary both to quantify the subsequent psychological effects of assisted reproduction as well as to assist in the selection of participants. Research is needed, for example, to determine whether couples seeking assisted reproduction have special psychological problems that would render them unfit candidates for treatment.

No widely accepted psychological criteria currently exist that couples seeking a child must meet before they can be considered as participants in an assisted reproduction program. Neither, of course, are there standard criteria for a couple seeking a child by means of intercourse. Establishing criteria for couples desiring to undertake assisted reproduction may permit caregivers to impose their values on the selection process—raising questions about who should be involved in and responsible for developing such criteria (17). Yet such criteria have been assessed as useful for helping to guide the behavior of the caregiver assisting a couple. Criteria could include the following (14):

- The presence of a stable psychosocial environment. An applicant couple on the brink of divorce, for example, would be poor candidates. Likewise, applicants troubled by addictive behaviors (i.e., drug or alcohol abuse) would be unsuitable.
- Evidence of authentic motivation. Each spouse should be participating because of the desire to raise a child, and not, for example, under the threat of divorce if he or she did not participate.

Research is needed on the predictive validity of these criteria, as well as on useful criteria for other participants in assisted reproduction, particularly the genetic parents (the donors).

A final critical question is how an infertile couple resolve their childlessness if infertility persists and adoption is rejected. What are the developmental factors, thought processes, or emotional involvement necessary to accept childlessness? What are the societal attitudes that affect a couple's ability to live contently without children? It is especially important to identify the treatment strategies that mental health professionals can bring to bear to assist a couple in the resolution of this final stage of infertility.

SUMMARY AND CONCLUSIONS

Two reproductive technologies first applied to humans within the past decade are today helping a small, but measurable, fraction of infertile couples form families and will continue to do so for the foreseeable future. The chances of achieving a successful pregnancy in the hands of the most expert practitioners are estimated to be about 15 to 20 percent for one completed IVF cycle and about the same for one completed attempt at gamete intrafallopian transfer. The number of infertile couples offered these techniques is likely to increase in the future as the techniques are applied to infertility of more varied causes than at present. The once-promising technique of uterine lavage to retrieve a fertilized ovum, followed by embryo transfer, is unlikely to continue to be offered to infertile couples.

The next decade will likely see the proliferation of embryo freezing as an adjunct to IVF, although early success with freezing eggs would likely preclude embryo freezing. Freezing eggs, however, stands as a formidable technical task and may involve an insurmountable biological obstacle—damage to the fragile chromosomes of the oocyte.

Researchers seeking to examine fertilization of human sperm and eggs, fertilized ova, or early embryos face a de facto moratorium on funding of such investigations by the Department of Health and Human Services, unless the study is directly related to IVF carried out as part of an infertile couple's routine clinical care. Research to study, for example, why some sperm do not fertilize eggs, or why some eggs are not fertilizable, is not funded by the National Institutes of Health.

Successful pregnancies following microinjection of a single sperm into an egg—recorded in neither animals nor humans, to date—would mark dramatic progress in the treatment of male factor infertility, most of which is caused by too few or abnormal sperm.

Reliable separation of X- and Y-bearing sperm for sex selection remains elusive despite many such attempts. When sex selection of sperm cells becomes possible, its use will be limited by the willingness of couples to undergo artificial insemination. The development and use of techniques to sex human embryos is likely to be retarded because such techniques involve splitting embryos into one part for sexing and another part for transfer. Research on nonhuman preimplantation embryos may lead to alternative approaches for the sexing of embryos.

Techniques for screening sperm and ova donors for a limited number of genetic anomalies lie in the foreseeable future. The practical application of genetic screening by practitioners of artificial insemination is uncertain, however, and no amount of screening will exclude all donors capable of transmitting genetic disorders.

The health of infants conceived by IVF or by gamete intrafallopian transfer and that of their mothers does not appear to deviate from norms for comparable populations. Because of the small numbers of individuals that have used these technologies to date, however, such estimates are necessarily preliminary, and ongoing surveillance would be prudent. Similarly, studies of the psychology of participants in assisted reproduction—particularly the children—are warranted.

This brief review of selected reproductive technologies and areas of reproductive research suggests that, while Aldous Huxley's vision of a *Brave New World* has not been realized, some frontiers of reproductive technology have been broached and others are being approached. As a result, infertile couples today have a wider range of options than before, and some of today's babies already have a qualitatively different pedigree. One noted science fiction writer recently offered his view of what the pedigree of tomorrow's babies might look like (see box 15-B).

Box 15-B.—A Look Ahead

Commonwealth of California, Department of Health's Vital Records
CERTIFICATE OF LIFE

Subject:	Baby Boy, Miller
Date of Conception:	Nov. 15, 2018, 12:15 p.m.
Place:	Comprehensive Fertility Institute, Beverly Hills, CA
Number of Parents:	Three, including surrogate mother—mother donated egg, father sperm
Method of Conception:	In vitro fertilization followed by embryo transfer. Mother's body had rejected her artificial fallopian tube. After 8 days on Pergonal, mother produced two eggs. Both were removed during routine laparoscopy and screened for possible defects. Eggs united with father's sperm. After 48 hours in incubator, embryos were removed from growth medium and placed in surrogate's womb. Only one embryo attached itself to uterine wall.
Prenatal Care:	Ultrasound at 3 months. Fetal surgery performed at 5 months.
Date/Time of Birth:	Jason Lawrence Miller born July 20, 2019, 4:15 a.m.
Father:	Jason L. Miller, Sr.
Mothers:	Amy Wong (natural); Maribeth Rivers (surrogate)
Birth Method:	Newly lifed in Morningstar Birthing Center, division of Humana Corporation. Natural delivery after 5-hour labor. Labor pains controlled though acupuncture. Therapeutic touch used for last hour of labor. Child's father, adopted sister, and natural mother attended the delivery.
Weight/Length:	10 lb.; 25 in.
Eye Color:	Green
Projected Life Span:	82 years

SOURCE: Adapted from A.C. Clarke, *July 20, 2019: Life in the 21st Century* (New York, NY: Macmillan, 1986).

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Appendixes

Appendix A

Sites Offering IVF/GIFT in the United States

The following 169 facilities in 41 States, Puerto Rico, and the District of Columbia, are reported to be accepting referrals or are actively engaged in in vitro fertilization (IVF) or gamete intrafallopian transfer (GIFT) as of March 1988, according to the American Fertility Society and other sources.

Alabama

IVF Australia at Birmingham
Women's Medical Plaza, Suite 508
2006 Brookwood Medical Center Drive
Birmingham, AL 35209
205-870-9784

University of Alabama-Birmingham Medical Center
Laboratory for In Vitro Fertilization-Embryo Transfer
547 Old Hillman Building, University Station
Birmingham, AL 35294
205-934-5631

IVF/GIFT Program
University of South Alabama
Room 326
Cancer Center Clinical Science Building
Mobile, AL 36688
205-460-7173

Arizona

Arizona Center for Fertility Studies
In Vitro Fertilization Program
4614 E. Shea Boulevard, D-260
Phoenix, AZ 85028
602-996-7896

Arizona Fertility Institute
2850 N. 24th Street, Suite 500A
Phoenix, AZ 85008
602-468-3840

Phoenix Fertility Institute P.C.
Good Samaritan Hospital
1300 North 12th Street, Suite 522
Phoenix, AZ 85006
602-252-8628

The Reproductive Institute of Tucson
El Dorado Medical Center
Tucson Medical Center, Bldg. 800
5200 East Grant Road
Tucson, AZ 85712
602-325-0802

California

Alta Bates Hospital
In Vitro Fertilization Program
3001 Colby Street
Berkeley, CA 94705
415-540-1416

Berkeley-East Bay Advanced Reproductive Service
2999 Regent Street, Suite 201
Berkeley, CA 94705
415-841-5510

Central California In Vitro Fertilization Program
Fresno Community Hospital
P.O. Box 1232
Fresno, CA 93715
209-439-1914

Fertility Institute of San Diego
Sharp/Children's Medical Center
9834 Genessee Avenue, Suite 300
La Jolla, CA 92037
619-455-7520

Scripps Clinic and Research Foundation
10666 N. Torrey Pines Road
La Jolla, CA 92037
619-457-8680

University of California at Irvine Memorial Hospital
2880 Atlantic Avenue, Suite 220
Long Beach, CA 90806
213-595-2229

California Reproductive Health Institute
Division of In Vitro Fertilization
California Medical Hospital
1338 S. Hope Street
Los Angeles, CA 90015
213-742-5970

Cedars-Sinai Medical Center
444 San Vicente Boulevard, Suite 1101
Los Angeles, CA 90045
213-855-2150

Century City Hospital
2070 Century Park East
Los Angeles, CA 90067
213-201-6604

Southern California Fertility Institute
California Institute for In Vitro Fertilization, Inc.
Right to Parenthood Program
12301 Wilshire Boulevard, Suite 415
Los Angeles, CA 90025
213-820-3723

Tyler Medical Clinic
921 Westwood Boulevard
Los Angeles, CA 90024
213-208-6765

University of California—Los Angeles School of Medicine
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
Los Angeles, CA 90024
213-825-7755

University of California—Irvine
Department of Obstetrics and Gynecology
101 The City Drive
Orange, CA 92668
714-638-1500

South Bay-AMI Hospital
In Vitro Fertilization Center
415 North Prospect Avenue
Redondo Beach, CA 90277
213-318-4741

Northern California Fertility Center
87 Scripps Drive, Suite 202
Sacramento, CA 95825
916-929-3596

Pacific Fertility Center
2100 Webster Street, Suite 220
San Francisco, CA 94120
415-923-3344

University of California, San Francisco
In Vitro Fertilization Program
Department of Obstetrics and Gynecology and Reproductive Sciences
Room M 1480
San Francisco, CA 94143
415-666-1824

Stanford University
Department of Obstetrics and Gynecology
S-385 Medical Center
Stanford, CA 94305
415-723-5251

Fertility Medical Group of the Valley
In Vitro Fertilization Program-Northridge Hospital
18370 Burbank Boulevard, Suite 301
Tarzana, CA 91356
818-946-2289

John Muir Memorial Hospital
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
1601 Ygnacio Valley Road
Walnut Creek, CA 94598
415-937-6166

Whittier Hospital Medical Center
The Genesis Program for In Vitro Fertilization
Center for Human Development
15151 Janine Drive
Whittier, CA 90605
213-945-3561, ext. 549

Colorado

Reproductive Genetics In Vitro
455 South Hudson Street
Level Three
Denver, CO 80222
303-399-1464

University of Colorado Health Sciences Center
In Vitro Fertilization Program
4200 East 9th Avenue
Box B198
Denver, CO 80262
303-394-8365

Connecticut

University of Connecticut Health Center
Division of Reproductive Endocrinology & Infertility
Farmington, CT 06790
203-674-2110

Mount Sinai Hospital
Department of Obstetrics and Gynecology
Division of Reproductive Endocrinology and Infertility
675 Tower Avenue
Hartford, CT 06112
203-242-6201

Yale University Medical Center
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
333 Cedar Street
New Haven, CT 06510
203-785-4019, 785-4792

Delaware

The Medical Centre of Delaware
Reproductive Endocrine and Infertility Center
P.O. Box 6001
4755 Stanton-Ogletown Road
Newark, DE 19718
302-733-2318

District of Columbia

Columbia Hospital for Women Medical Center
In Vitro Fertilization Program
2425 L Street, N.W.
Washington, DC 20037
202-293-6500

George Washington University Medical Center
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
901 23rd Street, N.W.
Washington, DC 20037
202-994-4614

Florida

Shands Hospital
University of Florida
In Vitro Fertilization Center
Gainesville, FL 32610
904-395-0454

Fertility Institute of Northwest Florida
Gulf Breeze Hospital
1110 Gulf Breeze Parkway, Suite 202
Gulf Breeze, FL 32561
904-934-3900

Memorial Medical Center of Jacksonville
In Vitro Fertilization Program
3343 University Boulevard South
Jacksonville, FL 32216
904-391-1149

IVF Florida
HCA Northwest Regional Hospital
5801 Colonial Drive
Margate, FL 33063
305-972-5001

Mount Sinai Medical Center
University of Miami
4300 Alton Road
Miami Beach, FL 33140
305-674-2139

University of Miami
Department of Obstetrics and Gynecology: D-5
P.O. Box 016960
Miami, FL 33101
305-547-5818

Naples Life Program
775 First Avenue North
Naples, FL 33940
813-262-1653

Orlando Regional Medical Center
Sand Lake Hospital
9400 Turkey Lake Road
Orlando, FL 32819-8001
305-351-8537

Florida Fertility Institute
Palms of Pasadena Hospital
3451 66th Street, North
St. Petersburg, FL 33710
813-384-4000

Humana Women's Hospital
University of South Florida
3030 West Buffalo Avenue
Tampa, FL 33607
813-872-2988

Georgia

Reproductive Biology Associates
993-D Johnson Ferry Road, N.E., Suite 330
Atlanta, GA 30342
404-843-3064

Augusta Reproductive Biology Associates
810-812 Chafee
Augusta, GA 30904
404-724-0228

Humana Hospital
2 East, 3651 Wheeler Rd.
Augusta, GA 30910
404-863-6234

Hawaii

Pacific In Vitro Fertilization Hospital
Kapiolani Women's and Children's Hospital
1319 Punahou Street, Suite 1040
Honolulu, HI 96826
808-946-2226

Kauai Medical Group, Inc.
University of Hawaii
G.N. Wilcox Memorial Hospital
Department of Obstetrics and Gynecology
3420-B Kuhio Highway
Lihue, HI 96766

Illinois

Michael Reese Hospital and Medical Center
In Vitro Fertilization-Embryo Transfer Program
31st Street at Lake Shore Drive
Chicago, IL 60616
312-791-4000

Mount Sinai Hospital Medical Center
Department of Obstertrics and Gynecology
In Vitro Fertilization Program
California Avenue at 15th Street
Chicago, IL 60608
312-650-6727

Northwestern Memorial Hospital
In Vitro Fertilization Program
Prentice Womens Hospital
333 East Superior Street, Suite 454
Chicago, IL 60611
312-908-1364

Rush Medical College
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
600 South Paulina Street
Chicago, IL 60616
312-942-6609

University of Illinois College of Medicine
Department of Obstetrics and Gynecology
840 South Wood Street
Chicago, IL 60612
312-996-7430

The Glenbrook Hospital
Northwestern Univerity
In Vitro Fertilization Program
2100 Pfingsten Road
Glenview, IL 60025
312-729-6450

Indiana

Indiana University Medical Center
Department of Obstetrics and Gynecology—
Reproductive Endocrinology
926 West Michigan Street, N-262
Indianapolis, IN 46223
317-264-4057

Pregnancy Initiation Center
Humana Womens Hospital
8091 Township Line Road, Suite 110
Indianapolis, IN 46260
317-872-5103

Iowa

University of Iowa Hospitals and Clinics
IVF-ET GIFT Program
Iowa City, IA 52242
319-356-1767

Kansas

University of Kansas College of Health Sciences
Obstetrics and Gynecology Foundation
39th and Rainbow Boulevard
Kansas City, KS 66103
913-588-6246

Kentucky

University of Kentucky
Department of Obstetrics and Gynecology
Kentucky Center for Reproductive Medicine
Lexington, KY 40536
606-233-5410

Norton Hospital
In Vitro Fertilization Program
601 Floyd Street, Room 304
Louisville, KY 40202
502-562-8154

Louisiana

Fertility Center of Louisiana
St. Jude Medical Center
200 West Esplanade Drive
Kenner, LA 70065
504-464-8622

Omega Institute
Elmwood Medical Center
4425 Conlin Street, Suite 101
Metairie, LA 70006
800-535-4177

Fertility Institute of New Orleans
Humana Women's Hospital
6020 Bullard Avenue
New Orleans, LA 70128
504-246-8971

Tulane Fertility Program
In Vitro Fertilization Program
1415 Tulane Avenue
New Orleans, LA 70112
504-587-2147

Maryland

Baltimore In Vitro Fertilization Program
2435 West Belvedere Avenue, Suite 41
Baltimore, MD 21215
301-542-5115

Greater Baltimore Medical Center
Women's Fertility Center
In Vitro Fertilization Program
6701 N. Charles Street
Baltimore, MD 21204
301-828-2484

The Johns Hopkins Hospital
Division of Reproductive Endocrinology
In Vitro Fertilization Program
600 N. Wolfe Street
Baltimore, MD 21205
301-955-2016

Union Memorial Hospital
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
201 E. University Parkway
Baltimore, MD 21218
301-235-5255

Genetic Consultants
Washington Adventist Hospital
5616 Shields Drive
Bethesda, MD 20817
301-530-6900

Montgomery Fertility Institute
10215 Fernwood Road, Suite 303
Bethesda, MD 20817
301-897-8850

Massachusetts

Beth Israel Hospital
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
330 Brookline Avenue
Boston, MA 02215
617-732-5923

Brigham and Womens Hospital
In Vitro Fertilization Program
75 Francis Street
Boston, MA 02115
617-732-4239

In Vitro Fertilization Center of Boston
Boston University Medical Center
75 East Newton Street
Boston, MA 02118
617-247-5928

New England Medical Center Hospitals
Division of Reproductive Endocrinology
260 Tremont Street
Boston, MA 02111
617-956-6066

Boston IVF
25 Boylston Street
Chestnut Hill, MA 02167
617-735-9000

Greater Boston In Vitro Associates
Newton-Wellesley Hospital
2000 Washington Street, Suite 342
Newton, MA 02162
617-965-7270

Michigan

Hutzel Hospital
In Vitro Fertilization Program
Wayne State University
4707 St. Antoine
Detroit, MI 48201
313-494-7547

Blodgett Memorial Medical Center
In Vitro Fertilization Program
1900 Wealthy Street S.E., Suite 330
Grand Rapids, MI 49506
616-774-0700

William Beaumont Hospital
In Vitro Fertilization Program
3601 West 13 Mile Road
Royal Oak, MI 48072
313-288-2380

Saginaw General Hospital
In Vitro Fertilization Program
Saginaw, MI 48603
517-771-4562

Minnesota

University of Minnesota VIP Program
Department of Obstetrics and Gynecology
Mayo Memorial Building, Box 395
420 Delaware Street, S.E.
Minneapolis, MN 55455
612-373-7693

Mayo Clinic
Department of Reproductive Endocrinology and Infertility
200 First Street, S.W., W-10
Rochester, MN 55905
507-284-7367

Mississippi

University of Mississippi Medical Center
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
Jackson, MS 39216
601-984-5300

Missouri

St. Luke's Hospital
In Vitro Fertilization, Gamete Intrafallopian Transfer Program
44th and Wornall Road
Kansas City, MO 64111
816-756-0277

Jewish Hospital of St. Louis
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
216 S. Kingshighway
St. Louis, MO 63110
314-454-7834

Missouri Baptist Hospital
In Vitro Fertilization Program
3015 N. Ballas Road, Room 301
St. Louis, MO 63131
314-432-1212, ext. 5295

Silber and Cohen
224 South Woods Mill Road
Suite 730
St. Louis, MO 63017
314-576-1400

Nebraska

University of Nebraska Medical Center
Department of Obstetrics and Gynecology
42nd and Dewey Avenue
Omaha, NE 68105
402-559-4212

Nevada

Northern Nevada Fertility Clinic
350 West 6th Street
Reno, NV 89503
702-322-4521

New Jersey

UMDNJ-School of Osteopathic Medicine
In Vitro Fertilization Program
401 Hadden Avenue
Camden, NJ 08103
609-757-7730

UMDNJ-Robert Wood Johnson Medical School
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
1 Robert Wood Johnson Place, CN19
New Brunswick, NJ 08903
201-937-7627

UMDNJ-University Hospital
Center for Reproductive Medicine
100 Bergen Street
Newark, NJ 07103
201-456-6029

New Mexico

Presbyterian Hospital
In Vitro Fertilization Program
Cedar Street Southwest
Albuquerque, NM 87106
505-841-4214

New York

Childrens Hospital of Buffalo
Reproductive Endocrinology Unit
140 Hodge Avenue
Buffalo, NY 14222
716-878-7232

Albert Einstein College of Medicine
In Vitro Fertilization Center at Womens Medical Pavilion
88 Ashford Avenue
Dobbs Ferry, NY 10522
914-693-8820

North Shore University Hospital
Division of Human Reproduction: In Vitro Fertilization
300 Community Drive
Manhasset, NY 11030
516-562-4470

Advanced Fertility Services PC
1625 Third Avenue
New York, NY 10028
212-369-8700

Columbia-Presbyterian Medical Center
Presbyterian Hospital In Vitro Fertilization Program
622 West 168th Street
New York, NY 10032
212-694-8013

Cornell University Medical College
In Vitro Fertilization Program
515 East 71st Street, 2nd Floor
New York, NY 10021
212-472-4693

Mount Sinai Medical Center
In Vitro Fertilization Program
One Gustave Levy Place
Annenberg 20-60
New York, NY 10029
212-241-5927

St. Luke's-Roosevelt Hospital Center
In Vitro Fertilization-Embryo Transfer Program
1111 Amsterdam Avenue
New York, NY 10025
212-870-6603

Wayne H. Decker In Vitro Fertilization Program
1430 Second Avenue, Suite 103
New York, NY 10021
212-744-5500

IVF Australia at United Hospital
406 Boston Post Road
Port Chester, NY 10573
914-934-7481

University of Rochester CARE Program
University of Rochester Medical Center
601 Elmwood Avenue
Rochester, NY 14642
716-275-2384

North Carolina

Chapel Hill Fertility Services
109 Conner Drive, Suite 2104
Chapel Hill, NC 27514
919-968-4656

University of North Carolina Medical School
Fertility Center
Division of Endocrinology and Infertility
Department of Obstetrics and Gynecology: 226H
Chapel Hill, NC 27514
919-966-5282

Duke University Medical Center
Department of Obstetrics and Gynecology
P.O. Box 3143
Durham, NC 27710
919-684-5327

Ohio

Akron City Hospital
In Vitro Fertilization-Embryo Transfer Program
525 East Market Street
Akron, OH 44309
216-375-3585

Jewish Hospital of Cincinnati
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
3120 Burnet Avenue, Suite 204
Cincinnati, OH 45229
513-221-3062

University of Cincinnati Medical Center
Division of Reproductive Endocrinology
231 Bethesda Avenue, ML 526
Cincinnati, OH 45267
513-872-5046

Cleveland Clinic Foundation
In Vitro Fertilization Program
9500 Euclid Avenue
Cleveland, OH 44106
216-444-2240

MacDonald Hospital for Women
In Vitro Fertilization Program
2105 Adelbert Road
Cleveland, OH 44106
216-844-1514

Mount Sinai Medical Center
LIFE Program
University Circle
Cleveland, OH 44106
216-421-5884

Infertility and Gynecology
St. Anthony Hospital
1492 E. Broad Street
Columbus, OH 43205
614-253-8383

Midwest Reproductive Institute
1409 Hawthorne Avenue
Columbus, OH
614-253-0003

University Reproductive Center
Ohio State University Hospitals
410 West 10th Avenue
Columbus, OH 43210
614-421-8937; 421-8511

Miami Valley Hospital
In Vitro Fertilization Program
1 Wyoming Street
Dayton, OH 45409
513-223-6192, ext 4066

Oklahoma

Henry G. Bennett Fertility Institute
Baptist Medical Center of Oklahoma
3433 NW 56th, Suite 200
Oklahoma City, OK 73112
405-949-6060

Oklahoma University Health Sciences Center
Section of Reproductive Endocrinology
P.O. Box 26901, 4SP720
Oklahoma City, OK 73190
405-271-8700

Hillcrest Fertility Center
1145 South Utica, Suite 1209
Tulsa, OK 74104
918-584-2870

Oregon

Oregon Health Sciences University
Oregon Reproductive Research and Fertility Program
3181 SW Sam Jackson Park Road
Portland, OR 97201
503-279-8449

Pennsylvania

Hospital of the University of Pennsylvania
Department of Obstetrics and Gynecology
3400 Spruce Street, Suite 106
Philadelphia, PA 19104
215-662-2981

The Pennsylvania Hospital
In Vitro Fertilization-Embryo Transfer Program
Eighth and Spruce Streets
Philadelphia, PA 19107
215-829-5018

Albert Einstein Medical Center
Department of Obstetrics and Gynecology
York and Tabor Roads
Philadelphia, PA 19141
215-456-7990

St. Luke's Hospital
In Vitro Fertilization Program
801 Ostrum Street
Bethlehem, PA 18015
215-691-7323

Christian Fertility Institute
241 North 13th Street
Easton, PA 18042
215-250-9700

Women's Clinic Ltd.
In Vitro Fertilization Program, Suite 385
301 S. 7th Avenue
W. Reading, PA 19611-1499
215-374-7797

Puerto Rico

Hospital San Pablo
Edificio Medico Santa Cruz
73 Santa Cruz, Suite 213
Bayamon, PR 00619
809-798-0100

Rhode Island

Women's & Infant's Hospital of Rhode Island
In Vitro Fertilization Program
Providence, RI 02905
401-274-1100

South Carolina

Medical University of South Carolina
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
171 Ashley Avenue
Charleston, SC 29425
803-792-2861

The Southeastern Fertility Center
Trident Regional Medical Center Hospital
315 Calhoun Street
Charleston, SC 29401
803-722-3294

Tennessee

East Tennessee State University
Department of Obstetrics and Gynecology
P. O. Box 19570A
Johnson City, TN 37614
615-928-6426, ext. 334

East Tennessee Baptist Hospital
Family Life Center
7A Office 715
Box 1788, Blount Avenue
Knoxville, TN 37901
615-632-5697

University of Tennessee Memorial Research Center and Hospital
1924 Alcoa Highway
Knoxville, TN 37920
615-971-4958

Vanderbilt University
In Vitro Fertilization Program
D-3200 Medical Center North
Nashville, TN 37232
615-322-6576

Texas

St. David's Community Hospital
In Vitro Fertilization-Embryo Transfer Program
P.O. Box 4039 (1302 West 38th Street)
Austin, TX 78765
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Texas Endocrine and Fertility Institute
Trinity Medical Center
4323 North Josey Lane, Suite 206
Carrollton, TX 75010
214-394-0114

Presbyterian Hospital of Dallas
P.O. Box 17 (8160 Walnut Hill Lane)
Dallas, TX 75231
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The University of Texas-SW Medical School
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
5323 Harry Hines Blvd
Dallas, TX 75230
214-688-2784

Fort Worth Infertility Center
Harris Institute
1325 Pennsylvania Avenue, Suite 750
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Baylor College of Medicine
Department of Obstetrics and Gynecology
In Vitro Fertilization Program
1 Baylor Plaza
Houston, TX 77030
713-791-2033

Memorial Reproductive Services
7600 Beechnut
Houston, TX 77074
713-776-5514

Texas Woman's Hospital
7600 Fannin
Houston, TX 77054
713-795-7257

University of Texas Health Science Center
Department of Reproductive Science
6431 Fannin, Suite 3204
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713-792-5360

University of Texas Medical Branch
Department of Obstetrics and Gynecology:
In Vitro Fertilization Program
Galveston, TX 77550
409-761-3985

The West Houston Fertility Center
Sam Houston Memorial Hospital
1615 Hillendahl Boulevard
P.O. Box 55130
Houston, TX 77055
713-932-5600

Texas Tech University Health Sciences Center
Department of Obstetrics and Gynecology
P. O. Box 4569
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806-743-2335

Humana Women's Hospital of South Texas
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University of Texas Health Science Center
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Vermont

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802-656-2272

Virginia

University of Virginia Medical Center
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Genetics and IVF Institute
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Eastern Virginia Medical School
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1602 Skipwith Road
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804-289-4315

Medical College of Virginia
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Washington

Swedish Hospital Medical Center
Reproductive Genetics
747 Summit Avenue
Seattle, WA 98104
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University of Washington In Vitro Fertilization Program
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Infertility and Reproductive Associates
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Spokane, WA 99204

Fertility Center of Puget Sound
3rd Floor, Puget Sound Hospital
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Tacoma, WA 98408
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Appleton Medical Center
Family Fertility Program
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Appleton, WI 54911
414-731-4101, ext. 3380

University of Wisconsin Clinics
In Vitro Fertilization Program
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Madison, WI 53792
608-263-1217

University of Wisconsin-Milwaukee Clinical Campus
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Mount Sinai Medical Center
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Waukesha, WI 53186
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Appendix B

Self-Administered Preconception Questionnaire

The following reproductive health questionnaire, developed at an OTA workshop held in Seattle, WA, is intended for self-administration by young adults. Each question is accompanied by an informative response. This particular questionnaire is presented solely for illustrative purposes and has not been tested or validated. It is intended to illustrate the type of questionnaire that could identify men and women who may have a problem that might render them infertile in the future (1).

Questions for Men

Do you feel that having children is very important to your goals in life?

If you do, you should develop 5- and 10-year life plans that will include the opportunity to conceive and have children.

Have you considered the role of children in a marriage and, if you are in a long-term relationship, reached an understanding regarding number of children and when you plan to have them?

If you are involved in a significant relationship, you should initiate discussion on these issues.

Have you had unprotected intercourse for more than 1 year without your partner becoming pregnant?

You or your partner may be infertile.

True (yes) or false (no), a woman is only fertile 1 day a month?

If you answered no, you may misunderstand the relationship between the timing of sex and pregnancy. Seek further information.

Have both of your testes been in your scrotum since birth? If not, have you had surgery or hormonal treatment?

Consult your physician.

Are you experiencing, or have you experienced, frequent urination or a discharge or burning during urination?

You may have an infection that could affect your future fertility and that of women with whom you have had sex. See your physician and tell your sex partner(s) to see one also.

Is one of your testes significantly larger than the other?

You could have a low sperm count. Consult your physician.

Have you ever had a lump in the groin, or significant pain of the testes or scrotum?

This lump or pain may indicate that you may have problems producing sperm. Consult your physician.

Have you ever noticed an extra fullness or pressure in the scrotum or been told that you have varicose veins in the scrotum?

You could have a varicocele or varicose veins in the scrotum. Consult your physician, who may examine your scrotum and do a semen analysis and sperm count.

Do you use alcohol, cigarettes, marijuana, cocaine, or prescription drugs?

Use of these products may reduce your fertility. Seek further information regarding their potential effects on your fertility.

Have you been exposed to radiation, chemotherapy, pesticides, or other chemicals, or to diethylstilbestrol (DES) when your mother was pregnant with you?

You could have decreased sperm production as a result of this exposure. Consult your physician, who may do a semen analysis and sperm count.

Have you ever had an operation on your testes or hernia repairs in the lower abdominal region?

You may have reduced fertility. Consult your physician.

Do you have more than 10 alcoholic drinks per week?

You may have semen abnormalities. Consult your physician, who may do a semen analysis and sperm count.

Do you frequently take hot tubs or saunas, or have other chronic heat exposure?

You may have reduced fertility.

Can you name all of your sexual partners?

Multiple sexual partners expose you to increased risk of acquired immunodeficiency syndrome (AIDS), gonorrhea, herpes, and other conditions *that can lead to infertility, significant illness, or even death. It is important to consider the consequences of your sexual activity.*

Have you had difficulty in achieving or sustaining penile erections (potency) or sexual arousal (libido) sufficient to successfully initiate or complete sexual intercourse?

You could have a problem with the functioning of your testes.

Have you ever been treated for cancer or lymphoma?

You could have a low sperm count. Consult your physician.

Following urination, do you continue to dribble a few drops of urine or stain your underwear with urine?

This might affect your general health or your potential fertility. You probably have an infection of the prostate gland. Consult with your physician, who will need to examine you and possibly prescribe antibiotics.

Do you know how to avoid getting a venereal disease?

Venereal disease can be minimized by limiting the number of sexual partners and by using barrier methods of contraception (i.e., condom, diahragm, or contraceptive sponge, in concert with foams or jellies).

Questions for Women

Do you feel that having children is very important to your goals in life?

If you do, you should develop 5- and 10-year life plans that will include the opportunity to conceive and have children.

Have you considered the role of children in a marriage and, if you are in a long-term relationship, reached an understanding regarding number of children and when you plan to have them?

If you are involved in a significant relationship, you should initiate discussion on these issues.

Have you had unprotected intercourse for more than 1 year without becoming pregnant?

You or your partner may be infertile.

True (yes) or false (no), a woman is only fertile 1 day a month?

If you answered no, you may misunderstand the relationship between the timing of sex and pregnancy. Seek further information.

Have you had a ruptured appendix and an appendectomy?

You may have pelvic adhesions reducing your fertility. Consult your physician.

Have you ever had profuse vaginal discharge associated with pelvic pain?

You may have a pelvic infection. Consult your physician to evaluate this history of infection.

Have you been exposed to radiation, chemotherapy, pesticides, or other chemicals, or to diethylstilbestrol when your mother was pregnant with you?

You may have an increased risk of pregnancy complications. Consult your physician for evaluation of DES exposure.

Is your weight significantly above or below what it should be?

Your fertility may be compromised. Seek information regarding a program for weight management.

Do you have a significant amount of pain with your periods or at the time of intercourse?

You may have endometriosis, a condition associated with infertility. Consult your physician.

Have you ever been treated for fallopian tube infection, fallopian tube inflammation (salpingitis), uterine infection, or pelvic inflammatory disease?

Fallopian tube infection can cause blocked or damaged fallopian tubes that prevent pregnancy.

Are you currently using an intrauterine device (IUD) for contraception?

You are at increased risk of tubal infection, which can cause infertility. If you are using the Dalkon shield, have it removed. If you are using another type of IUD, consult your physician.

Have you noticed any increase in the amount or thickness of hair on your face, chest, or abdomen?

You could have a common hormone imbalance that might effect your general health or your potential fertility. Consult your physician who might perform laboratory testing to identify a particular abnormality.

Have you ever had an episode of abdominal pain, abnormal vaginal discharge, fever, or bleeding within a few weeks of an abortion or delivery?

You may have had a fallopian tube infection.

Do you have a white or milky discharge from your nipples that can be increased with gentle pressure?

You may have an elevated prolactin level. Consult your physician for a simple blood test.

Can you name all of your sexual partners?

Multiple sexual partners expose you to increased *risk of AIDS, gonorrhea, herpes, pelvic inflammatory disease, and other conditions that can lead to infertility, significant illness, or even death. It is important to consider the consequence of your sexual activity.*

Do you exercise vigorously (e.g., swimming, running, bicycling) for more than 60 minutes daily?
You may be at risk for an ovulatory problem. If you menstruate less frequently than once every 40 days, consult your physician.

Has a sexual partner ever complained of burning during urination or pain at the time of ejaculation?
Your partner may have had a sexually transmitted disease he could pass to you. Consult your physician regarding evaluation for history of infection.

Do you smoke more than one pack of cigarettes per day?
Smoking may be associated with difficulty conceiving and carrying a successful pregnancy to term. Stop smoking!

Have you ever had a pregnancy in the fallopian tube (an ectopic pregnancy)?
You may have fallopian tube damage.

Are you considering postponing childbearing beyond age 30 for work, school, or other personal reasons?
Fertility decreases with age. You might wish to have children sooner.

Did you have your first menstrual period at the same time as your classmates?
If you had a delay of several years in the time of your first menstrual period, you are at risk of having problems with ovulation.

Do your mother or sisters have endometriosis?
You also may have endometriosis, a condition associated with infertility. Consult your physician regarding evaluation for endometriosis and a discussion of future plans for pregnancy.

Did you begin intercourse before the age of 20, have greater than 5 previous sexual partners, or a sexual partner with a genital infection or discharge?
Some sexually transmitted infections can produce fallopian tube damage.

Have you had any operations on your cervix such as cone biopsy, cervical freezing, or electrocautery?
Your cervical mucus quality may be poor, which may compromise your ability to get pregnant. Consult your physician for evaluation of your cervical mucus.

Have you ever had sexual relations with a man who you think might have been homosexual, bisexual, or a drug user?
You are at increased risk for AIDS. Consult your physician to decide whether you should have a test for AIDS.

Did your mother experience menopause before the age of 40?
You could also experience early menopause. Consult your physician.

Have you had two or more voluntary abortions?
Use effective birth control to prevent cervical injury, uterine scarring, or pelvic infection from repeated abortions.

Do your menstrual periods last longer than 6 days, come more frequently than every 24 days, or require the use of both a tampon and pad together to maintain cleanliness during your period?
These factors are associated with a lack of regular ovulation.

Do you know how to avoid getting a venereal disease?
Venereal disease can be minimized by limiting the number of sexual partners and by using barrier methods of contraception (i.e., condom, diaphragm, or contraceptive sponge, in concert with foams or jellies).

Of the following, which do you think may affect your fertility: weight loss, weight gain, dieting, exercise, hormone pills, or stress?
All these factors can prevent regular ovulation.

Appendix B Reference

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Appendix C

Fetal Research Laws Possibly Affecting IVF

ARIZONA: Arizona bans use of "any human fetus or embryo" in nontherapeutic research, but specifies that research on embryos "resulting from an induced abortion" is at issue. Since preimplantation embryos created in vitro do not result from "an induced abortion," this statute probably does not apply to embryo research designed to improve or extend in vitro fertilization (IVF). Artificial insemination followed by lavage for fertilized ovum retrieval and transfer might be covered.

CALIFORNIA: California bans research on the "product of conception" but is specific that the "aborted product of conception" is at issue. Thus this statute would not apply to preimplantation embryos that have not been transferred and implanted, for they cannot yet have been aborted. It is unclear whether it would apply to research on embryos created by artificial insemination and removed by lavage.

ILLINOIS: Illinois bans sale or experiments "upon a fetus produced by the fertilization of a human ovum by a human sperm unless such experimentation is therapeutic to the fetus thereby produced," making intentional violation of the section a misdemeanor. Yet, another section specifies that it is not "intended to prohibit the performance of in vitro fertilization."

Although this formulation leaves open several questions about what IVF activities might be allowed, the proscriptions of the statute are elsewhere directed to research activities with "fetuses." Since the preimplantation embryo is not clearly a fetus under Illinois law, the statute does not necessarily apply to embryo research.

LOUISIANA: Three statutes appear to apply to embryo research. First, Louisiana's IVF law (see ch. 13) specifically prohibits the use of IVF to create an embryo exclusively for the purpose of doing research. By its terms, however, the statute does not cover embryos created by artificial insemination and then recovered by lavage prior to implantation. Nevertheless, this statute is the most far-reaching with respect to discouraging embryo research.

Another statute makes "human experimentation" a crime, defining it to include "the conduct, on a human embryo or fetus in utero, of any experimentation or study except to preserve the life or to improve the health of said human embryo or fetus." This statute could be read to require that the embryo in question be in utero, which would exempt preimplantation embryos, for a subsequent section speaks of the "complete extraction or expulsion from its mother of a human embryo or fetus, irrespective of the duration of pregnancy."

The third statute bans experiments "on an unborn child . . . unless the experimentation is therapeutic to the unborn child." If "unborn child" is broadly construed, it could extend to preimplantation embryos. Arguments about the scope of this statute are moot, however, since it was struck down on vagueness grounds (see ch. 13).

MAINE: The Maine statute against donating or selling "any product of conception considered live-born for . . . any form of experimentation" is defined to mean a "product of conception after complete expulsion from the mother, irrespective of the duration of the pregnancy, which breathes or shows any other evidence of life, etc." This statute does not appear to refer to preimplantation embryos.

MASSACHUSETTS: The Massachusetts statute prohibits the use of "any live human fetus whether before or after expulsion from its mother's womb, for scientific, laboratory, research or other kind of experimentation." Since a preimplantation embryo is not easily defined as a "live human fetus," the statute would appear to place no barrier in the way of research with unimplanted embryos. Another section defines "live fetus" in terms of "the same medical standards as are used in determining evidence of life in a spontaneously aborted fetus at approximately the same stage of gestational development," thus reinforcing the notion that only embryos or fetuses that have implanted and initiated a pregnancy are subject to the statute's prohibitions on research.

A subsection of this statute penalizes a person who "shall knowingly sell, transfer, distribute or give away any fetus in violation of the provisions of this section." The next sentence reads: "For purposes of this section, the word 'fetus' shall include also an embryo or neonate." The meaning of "section" in this sentence is unclear. The most plausible reading is that it means the "subsection" in which it appears, addressing the sale and transfer of fetuses. It is also unclear whether the term "embryo" refers to fertilized eggs and zygotes or only to more fully developed embryos that have implanted in the uterine wall. If this expansive definition were taken to apply to every use of "fetus" in the statute, it would ban all research with preimplantation embryos. This seems the less plausible interpretation, especially in a criminal statute that ordinarily is narrowly construed.

MICHIGAN: Michigan bans use of a "live human embryo for nontherapeutic research if . . . the research substantially jeopardizes the life or health of the embryo." It also bans such use if the embryo is the subject of a planned abortion.

MINNESOTA: Minnesota makes it a gross misdemeanor to "use or permit the use of a living human conceptus for any type of . . . research or experimentation except to protect the life or health of the conceptus." However, it permits research "which verifiable scientific evidence has shown to be harmless to the conceptus."

Although this law appears explicit in its ban on research on embryos, it was passed in 1973 in reaction to *Roe v. Wade*, before IVF was even possible. It is possible that research on an unimplanted embryo that is not intended for implantation would be considered "harmless."

NEW MEXICO: New Mexico's statute on "Maternal, Fetal and Infant Experimentation" defines regulated research to include that involving IVF, but not IVF performed to treat infertility. This might seem to apply to research on discarded or nontransferred embryos or embryos created solely for research. Yet the operative section of the statute, which prohibits clinical research not meeting its provisions, applies only to clinical research "involving fetuses, live-born infants or pregnant women." Thus the restrictions possibly may not apply to extracorporeal embryo research, notwithstanding the broad definition of clinical research to include IVF.

NORTH DAKOTA: The North Dakota fetal research law is modeled on the Massachusetts law, with some organizational differences. The section prohibiting "live fetal experimentation" clearly does not apply to embryos that have not yet implanted.

A later section that prohibits the sale of fetuses also defines fetus to include "embryo or neonate." However, it appears that this expansive definition applies only to sales and transfers in violation of that section.

OHIO: Ohio prohibits "experiments upon the product of human conception which is aborted." Thus even though a "product of conception" would include fertilized eggs and preimplantation embryos, the statute's prohibition applies only to "aborted" embryos. Since embryos that have not yet been transferred to a uterus and implanted arguably are not "aborted," the most likely reading of this statute is that it would not apply to research on embryos in vitro. Its application to eggs fertilized by artificial insemination and recovered by lavage is unclear.

OKLAHOMA: Oklahoma also refers to use of an "unborn child" in research, but in language that clearly refers to the results of an abortion. Once again, unless preimplantation embryos created by artificial insemination can be considered aborted because they were recovered by lavage, the section would not apply.

RHODE ISLAND: Rhode Island's statute is similar to Massachusetts' and thus raises the same issues of scope and interpretation.

PENNSYLVANIA: Pennsylvania prohibits "any type of nontherapeutic experimentation upon any unborn child," making it a third degree felony. This would not appear to prevent embryo transfer after IVF. The status of research on discarded or nontransferred embryos is less clear and depends on whether preimplantation embryos are considered "unborn children."

UTAH: Utah also prohibits experimentation on "live unborn children." But the statute appears to be aimed at abortion, since it is included under a heading of abortion laws. As in the Oklahoma law, the provision would not likely apply to IVF embryos, and it is unclear if it could apply to embryos recovered by lavage.

Appendix D

Feminist Views on Reproductive Technologies

Feminist analyses largely consist of applying political, sociological, psychological, biological, and ethical analysis to the role of women in society. Just as individuals differ in their preferred political and ethical values, feminists differ in their analyses of women's roles, their approval or disapproval of those roles, and their recommendations for changing those roles (1-19). This diversity of views makes it impossible to state categorically that feminists as a group will approve or disapprove a particular application of a particular noncoital reproductive technique. Nevertheless, certain broad areas of agreement exist among most feminists (15), including the following:

- Women have been and are subordinated to men, a phenomenon rooted in women's roles as childbearers and childrearers. Subordination of certain classes and races has also taken place. Subordination of any group based on such characteristics is ethically undesirable. Feminists are particularly sensitive to the **interactions of class, race, and gender** in the exploitation of women.
- Feminist values emphasize the importance of **human relationships**, rather than ownership or traditional or legal kinship. A man does not own his wife or any other woman, nor does he have ownership rights over the children she bears. The relations people freely form with each other are to be valued and supported, whether or not they conform to a traditional family form.
- Women have full rights of **bodily autonomy**. Women have control over their bodies, gametes, conceptuses, and fetuses through birth. This is true whether or not there is a "right" to have children that can be expressed by having a "right" to medical services, gamete donation, surrogacy, or financial assistance in order to be able to have children. Feminists are concerned with the medicalization of pregnancy and childbirth, and the potential subordination of pregnant women's rights to State intervention ostensibly on behalf of the fetus. Further, the choice to prevent or allow conception and childbirth cannot be considered to be freely made if political and economic institutions make certain choices impractical or impossible.

Noncoital reproductive techniques pose a challenge to feminist analyses. They offer new possibilities for personal choice at the same time as they exacerbate possibilities for exploiting some women or reinforcing societal attitudes concerning the imperative of biological parenthood. Many feminists fear that opening reproductive options for some women may jeopardize women's freedoms overall.

These techniques (gamete intrafallopian transfer, in vitro fertilization (IVF), artificial insemination by donor, surrogate mothering) increase opportunities for conceiving, circumventing male partner absence or sterility, and for bringing a baby to term. When chosen freely, with accurate information about the likelihood of success and an appreciation of the physical, legal, and emotional risks, noncoital reproductive techniques increase an individual's opportunity to realize the goal of genetic or gestational parenthood. Further, in light of the difficulty of adopting a child, they may offer the only hope of forming a family quickly. At the same time, these techniques create new opportunities for isolating and exploiting certain portions of the population, such as surrogate mothers or gamete donors.

Many feminists question how often the choice to have children, and particularly biologically related children, is genuinely free, in light of the cultural milieu in which adult women in the United States have been raised. The decision to seek out these techniques can be motivated by sincere, informed, and voluntary personal desires or by considerations many feminists would like to see deemphasized. The latter include views that genetic linkages are essential to the creation of a genuine family, particularly for men, and that women must bear or somehow provide children for their husbands in order to experience their womanhood fully and meet the societal expectations of marriage, even if at great personal risk, inconvenience, or disinclination.

The development of these techniques entails research and experimentation that may ultimately increase options for procreation, such as making delayed childbearing more feasible. It also invites, however, extensive experimentation with women. Some assert that careerism and a philosophy of "science for the sake of science" encourage research and development of infertility treatments that require women to undergo unpleasant or risky procedures. Many feminists assert that this is exacerbated by the fact that the majority of the researchers and clinicians are male. The relative lack of research into the causes of male infertility, and the resulting dearth of causes identified or treatments offered, means that men are rarely subjected to the same strains of diagnosis and treatment, and so may lack the empathy necessary to appreciate fully the intrusiveness and degradation of many of the procedures. This may lead to an inappropriate degree of enthusiasm within the medical and scientific community for using these techniques. In addition, feminists note that some earlier advances in the area of contraception have actually led to infertility, such as the use of certain kinds of intrauterine devices. This history of interaction between medical advances and women's reproductive health leads many feminists to be skeptical of the success claimed by researchers for their techniques.

In addition, the use of these techniques usually involves medical personnel and procedures. Although welcoming opportunities to enhance the safety of childbearing and the health of infants, many feminists note that numerous physicians and hospitals have come to treat pregnancy as an abnormal, highly dangerous (almost diseased) state. On this basis, a number of hospitals and physicians have moved rapidly to introduce medical interventions that regard the woman as separate from her fetus, that treat the fetus as a separate patient with interests markedly different from and often opposed to the mother's, and that encourage invasive, painful, or dangerous procedures (e.g., internal fetal monitoring, in utero fetal therapy, or cesarean sections) that medicalize the process of birth. The diminution of women's authority to make decisions about the conduct of their pregnancies and childbirths concerns many feminists. This is a particularly sensitive point in the late 1980s, as the women's health movement finds itself just beginning to succeed in its efforts to persuade pregnant women to question more often the medical traditions surrounding childbirth, such as specific birthing positions or indications for fetal monitoring and cesarean section.

The developing techniques for infertility diagnosis and treatment also have potential application in areas that are quite troubling to many feminists. For example, artificial insemination allows manipulation of sperm before insemination, making preconception sex selection a possibility for the future. Given the fact that many cultures express a strong preference for boys, many feminists question whether sex selection should be permitted. While enhancing personal choice for an individual woman, it may have widespread implications for our perception of the relative values of a boy or girl, and even demographic effects should the technique become reliable and widely used. In general, feminists express great concern over the prospects for genetic diagnosis, selection, and manipulation made possible by the use of IVF and research on human embryos.

Some feminists argue that commercializing noncoital reproductive techniques makes them more available, and thus increases access and personal choice for those who can pay. For some women, they also create new ways to earn money, by selling gametes or embryos, or by gestating for a fee. A philosophy of mind-body dualism (which to some extent encourages a view of the body as an object, separate from the mind) supports the choice to use the body as an economic resource.

Other feminists, however, reject this dualism. They fear that commercialization invites a view of gametes, embryos, and even women as commodities to be banked, bought, sold, and rented as a means to procreation. As property, they may be subject to management, such as governmental or contractual regulation of the behavior of women who are pregnant for a fee. Commercializing embryos or pregnancy, so that custody goes to someone other than the woman giving birth, may exacerbate the view of the fetus and the woman as separate individuals with opposing interests. This in turn may further the view that the interests or bodily integrity of one must be sacrificed to the other. Finally, these techniques create one employment area, surrogacy, that will be exclusively occupied by women, especially those without opportunities to earn money in other ways. Thus what is viewed as an opportunity by some feminists may be viewed by others as an invitation to exploitation of poor or Third World women.

Overall, it is not possible to state whether feminists will oppose or support any particular noncoital reproductive technique, as there are many feminist voices and many motivations for the use of these techniques. Yet feminists generally oppose developments that explicitly restrict bodily autonomy, that subordinate the ties of pregnancy, childbirth, or childrearing to exclusively genetic or property claims, that limit use to certain classes of people or categories of family unit, or that directly exploit women.

Further, many feminists advocate an effort to provide nontechnological solutions where possible. These include making institutions more flexible in order to allow increasing integration of family life and public activities. This would allow both men and women to participate in childrearing, making it possible to choose to have children at a younger age. Nontechnological solutions also include providing education to prevent sexually transmitted diseases that lead to impaired fertility, helping people to adopt children of all races and ages, and decreasing the social pressures that lead many to feel unfulfilled if they do not or cannot have biologically related children.

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Appendix E

International Developments

Major reports on the ethical and legal aspects of noncoital reproductive technologies have been issued by governmental or nongovernmental bodies in Australia, Canada, the Federal Republic of Germany, France, Israel, South Africa, Sweden, and the United Kingdom. At least 33 other countries have had considerable professional or public debate concerning these technologies.

Several international organizations are also considering the issues raised by reproductive technologies, including the Council of Europe, the World Health Organization, the European Parliament, and the Feminist International Network of Resistance to Reproductive and Genetic Engineering (FINRRAGE). This appendix surveys countries and organizations as follows:

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Other National Efforts Regarding Noncoital Reproduction

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Bulgaria 347
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Egypt 348
Finland 348
German Democratic Republic 348
Greece 348
Hungary 348
Iceland 349
India 349
Ireland 349
Italy 349
Japan 349
Libya 350
Luxembourg 350
Mexico 350
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New Zealand 351
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Overall, the international trend is toward accepting artificial insemination by husband and by donor. If artificial insemination by donor is used with a husband's consent, the child is generally considered his irrefutably legitimate offspring. In vitro fertilization (IVF) is also widely accepted, if it is done for a married couple and donor gametes are not used. Surrogate motherhood and ovum donation have achieved far less widespread acceptance, and, even where permitted, are often not commercialized. Research on human embryos is neither universally accepted nor rejected; it is often an item of disagreement within individual countries.

MAJOR NATIONAL EFFORTS REGARDING NONCOITAL REPRODUCTION

Australia

There has been considerable activity in Australia surrounding novel reproductive techniques, including federal and state reports, state legislation, and professional self-regulation.

Three reports have been published on the federal level. In 1985, the Senate Standing Committee on Constitutional and Legal Affairs published a report on *IVF and the Status of Children* (12), examining the lack of uniformity in previous legislation establishing the status of IVF children and evaluating the significance of this lack. Also in 1985, the Family Law Council of the Attorney-General's Office published a report examining reproductive technology in Australia, entitled *Creating Children: A Uniform Approach to the Law and Practice of Reproductive Technology in Australia* (9). Both of these reports stated that there should be uniformity of law throughout Australia regarding the status of children born using donor gametes, and the Family Law Council further emphasized the need for uniform regulation of reproductive technologies.

In the same year, a bill prohibiting experiments involving the use of IVF embryos (the Human Embryo Experimentation Act, 1985) (7) was introduced to the senate. The bill, which would have prohibited experimentation on embryos, sparked considerable controversy and was referred to a senate select committee for deliberation. The committee solicited written submissions from a wide range of organizations and individuals with interest and expertise on the topic; it also conducted public hearings all over the country, taking testimony from 64 witnesses. The submissions and testimony are published in a series of volumes totaling more than 2,000 pages (8). In 1986 the committee released its final report, *Human Embryo Experimentation in Australia* (11).

Considerable action has also taken place on the state level regarding reproductive technology. In 1977, the Australian Law Reform Commission completed a series of reports urging that legislation be considered concerning artificial insemination. In 1982, the Australian states began taking independent action (10). Since then, official inquiries and committees concerned with noncoital reproductive techniques have been set up in every state, issuing numerous reports:

- New South Wales, New South Wales Law Reform Commission
  —Artificial Conception Discussion Paper 1: *Human Artificial Insemination* (November 1984) (84)
  —Artificial Conception Report 1: *Human Artificial Insemination* (November 1986) (85)
  —Artificial Conception Discussion Paper 2: *In Vitro Fertilization* (July, 1987) (86)
- Queensland, *Report of the Special Committee Appointed by the Queensland Government to Enquire into the Laws Relating to Artificial Insemination, In Vitro Fertilization and Other Related Matters* (March 1984) (97)
- South Australia, *Report of the Working Party on In Vitro Fertilization and Artificial Insemination by Donor* (January 1984) (114)
- Tasmania, Committee to Investigate Artificial Conception and Related Matters
  —*Interim Report* (December 1984)
  —*Final Report* (June 1985) (124)
- Victoria, Commission for the State of Victoria, Committee to Consider the Social, Ethical, and Legal Issues Arising from In Vitro Fertilization (under the direction of Professor Louis Waller)
  —*Interim Report* (September 1982)
  —*Issues Paper on Donor Gametes in IVF* (April 1983)
  —*Report on Donor Gametes in IVF* (April 1983)
  —*Report on the Disposition of Embryos Produced by In Vitro Fertilization* (April 1984) (128)
- Western Australia, Committee to Enquire into the Social, Legal, and Ethical Issues Relating to In Vitro Fertilization and Its Supervision
  —*Interim Report* (August 1984) (135)
  —*Report* (October 1986).

Most states have enacted uniform legislation clarifying the status of children born using donor gametes, but Victoria's action, in response to the Waller Commission, is the most extensive, imposing statutory control on the practice of IVF and artificial insemination by donor (85). In 1984, the Victorian legislature passed the Status of Children (Amendment) Act and the Infertility (Medical Procedures) Act. The Status of Children Act states a child born following artificial insemination or in vitro fertilization with donor gametes is the legitimate offspring of his or her mother and her consenting husband.

The Infertility (Medical Procedures) Act (Nos. 10122-10171, 1984) continues the Australian ban on sales of human tissues, including sperm, ova, and embryos, and outlaws cloning, fertilization of a human ovum with an animal gamete, use of children's gametes, mixing donor's and husband's sperm in artificial insemination by donor, and all commercial forms of surrogate motherhood. It also sets up a system of state regulation for donor insemination, IVF, freezing and experimenting on embryos, participant counseling, and recordkeeping. In addition, a Standing Review and Advisory Committee was created to monitor the use of experimental procedures and to study and report to the Government about new developments in this field. Most importantly, the act bans the production of embryos for research purposes and allows research on surplus embryos only if this has been approved by the Standing Review and Advisory Committee. Legislation to amend the act, arising out of recommendations made by the Standing Review and Advisory Committee on Infertility, was introduced into the Victorian Parliament in April 1987 and was scheduled for debate (133).

Australia has a national regulatory system concerned with ethical aspects of research on humans. This system is guided by the National Health and Medical Research Council (NHMRC), a body charged with advising federal, state, and territory governments and the Australian community on health-related matters (75). The NHMRC's regulatory system consists of two components, the Medical Research Ethics Committee (MREC) and a network of Institutional Ethics Committees (IECs). The MREC was constituted in 1982 as an advisory committee to the NHMRC, charged with recommending ethical principles to govern human experimentation and providing ethical guidelines for research in certain fields, supervising the work of the IECs, and maintaining dialogue with the Commonwealth and state ministers of health and attorneys general and to the community. The IECs are in-house ethics committees that have been established in all Australian hospitals and other institutions conducting research on humans (75).

The NHMRC guidelines consist of a general statement on human experimentation and a series of supplementary notes addressing ethical aspects of research in particular fields, each of which has been published separately with numerous supporting documents. The primary recommendation of the statement on human experimentation was the establishment of an Institutional Ethics Committee in any institution in which human experimentation takes place. The guidelines as a whole were published together in 1985 in the *NH&MRC Statement on Human Experimentation and Supplementary Notes* (82). The MREC continually reviews and updates the supplementary notes, in addition to preparing new reports on various topics. The supplementary notes of particular interest for this report are number 1, *Institutional Ethics Committees*, and number 4, *In-Vitro Fertilisation and Embryo Transfer*, discussed in greater detail later in this section.

In 1987, some 116 institutions were stated to be conducting medical research; all of them already conformed to the NHMRC guidelines or were making adjustments to do so (75).

Artificial Insemination

In 1983, the Family Law Act of 1975 was amended to state that a child conceived by a married woman using donor sperm with the consent of her husband is legitimate. In 1985, amendments to the Marriage of 1961 allowed recognition of this presumption of legitimacy if each state enacted the necessary legislation. Thus, the initiative was left to the states (85).

New South Wales (in the Artificial Conception Act, 1984), Victoria (in the Status of Children Act, 1984), South Australia (in the Family Relationships Amendment Act, 1984), Tasmania, Western Australia, the Australian Capital Territory, and the Northern Territory have all enacted legislation stating that children resulting from artificial insemination or IVF with donor gametes are the legitimate offspring of the mother and her consenting husband or partner (stable unmarried couples are included in this legislation). Queensland is in the process of enacting legislation related to artificial insemination (85).

The state committees and commissions listed earlier agree that artificial insemination by donor is acceptable in principle, provided donor screening and donor and recipient counseling are performed. All but the Victorian committee agreed that couples in stable relationships as well as married couples should have access to this technique (134). All but one committee specified that there should be a limit on the number of donations allowed, and all but two specified that payment should be limited to expenses. The committees were split on the issue of using known donors, while most of them agreed that recipients and children of donor sperm should have access to nonidentifying information about the donor. All of them urged proper recordkeeping at the institutional level, and most even recommended varying types of central registries to record information about gamete donors and children resulting from artificial insemination by donor and IVF.

Oocyte Donation

All six state committees found egg donation permissible, provided that proper screening and counseling are performed. All but two specified that payment for donation of oocytes should not be allowed (excepting reimbursement of expenses), and Victoria's Infertility (Medical Procedures) Act forbids the sale of human gametes. The recommendations concerning number of donations, anonymity, access to information, and recordkeeping are identical to those for sperm donation (134).

The NHMRC guidelines state that ovum donation is acceptable, provided proper consent is obtained and no payment occurs (82).

In Vitro Fertilization

All the state committees considered IVF acceptable in principle, both with and without donor gametes, provided it is being used on medical grounds and the couple receives counseling. All the committees agreed that the procedure should be made available to couples only, but the Waller Commission in Victoria further specified that marriage should be required (134).

Only the South Australia report forbade donation of embryos (114), although the Western Australian committee specified that embryo donation should be used only in rare cases (135).

On the federal level, the Family Law Council's recommendations were largely similar to those of the state reports—counseling should be required, adequate records should be kept, and donated gametes are considered acceptable (subject to better standards and guidelines). However, the Council did not approve the use of known related donors; known unrelated donors were considered acceptable. Furthermore, the Council recommended that children born from donor gametes have access to nonidentifying information about their genetic parents before the age of 18 and identifying information after 18 (9).

The NHMRC guidelines on IVF also agree that IVF is a justifiable means of treating infertility. However, they state that much research still needs to be done, and therefore certain rules should be followed. Most importantly, every institution offering IVF should have all aspects of the program approved by an institutional ethics committee. These committees must include at least five people—a laywoman, a layman, a minister, a lawyer, and a medical graduate with research experience. This committee must ensure that proper records are kept. Furthermore, the guidelines state that IVF should normally involve the ova and sperm of the partners (82).

In 1985, the MREC conducted a study of IVF centers and found that they were following the NHMRC guidelines. The only exceptions were that several of the IECs did not have proper lay representation (83).

Freezing and Storage of Human Sperm, Oocytes, and Embryos

Cryopreservation of oocytes was not universally accepted by the state committees as it was considered an experimental procedure. Legislation in Victoria forbids the procedure, as it would involve research on the resulting embryos to determine any deleterious effects (15). All the committees save the one in Western Australia, which did not resolve the issue (134), considered freezing embryos acceptable in principle but refrained from supporting oocyte freezing unconditionally until the technology improves. Only the commissions in Victoria and South Australian suggested a time limit for storage of frozen embryos (114,134).

The NHMRC guidelines approve cryopreservation of embryos, provided limits are set on the duration of storage (82). During their discussion of research on human embryos, the senate select committee on the Human Embryo Experimentation Act, 1985, stated that cryopreservation is acceptable if it maximizes the chance that the embryo will be implanted and carried to term (11).

Research on Preimplantation Embryos

Only the commissions in Victoria and Western Australia considered human embryo research acceptable (128,135). They considered excess embryos (i.e., those, left over from a therapeutic IVF attempt) to be the only acceptable source of embryos for research, and they set a time limit of 14 days on the duration of embryo culture. In Victoria, the Infertility (Medical Procedures) Act bans the production of embryos solely for research and allows research on surplus embryos only if the specific experiment has been approved by the Standing Review and Advisory Committee (134). At the federal level, the Family Law Council report opposed all research on human embryos (9).

The NHMRC guidelines find research on embryos acceptable up to the stage at which implantation would normally occur, provided each experiment is approved by the appropriate IEC. Cloning is rejected outright (82).

In its 1986 report, the senate select committee on the Human Embryo Experimentation Act, 1985, recommended that experiments designed to help an embryo be allowed but that all experiments resulting in the destruction of an embryo be outlawed. The committee did not find the currently operating system of IECs adequate, nor did it support the criminal law approach of the proposed bill. Instead, the committee recommended an accreditation and licensing scheme to assess each experiment on a case-by-case method. A dissenting minority argued that embryo research should not be restricted to therapeutic experimentation only (11).

Surrogate Mothers

Four of the state committees rejected surrogacy arrangements unconditionally—South Australia, Tasmania, Victoria, and Western Australia—and the Queensland report opposed commercial surrogacy and suggested that legislation should ensure that the birth mother remained the mother of the child (97,114,124,134,135). The New South Wales Law Reform Commission has not yet addressed the question of surrogacy, but the practice is effectively illegal in New South Wales as it is illegal for a mother giving up a baby for adoption to designate to whom the baby should be given (105). Commercial forms of surrogacy are also illegal under Victoria's Infertility (Medical Procedures) Act.

The Family Law Council report stated that surrogacy is contrary to the interests and welfare of the child (9), and the NHMRC guidelines state that surrogacy is not ethically acceptable (82).

Canada

Canada is a federation of 10 provinces and two territories. Under Canada's federal system, provinces and territories are responsible for the provision of health care. National health insurance is provided in Canada through a series of interlocking provincial and territorial plans, sharing common elements. Insured services vary from province to province, but a fairly comprehensive range is provided by all provinces (91).

To qualify for federal financial support, provincial hospital and medical care insurance plans must meet minimum criteria of federal legislation: comprehensiveness of coverage of services, portability of benefits, and nonprofit plan administration by a public agency. The plans are designed to ensure that all residents of Canada have access, on a prepaid basis, to needed medical and hospital care. In general, medical and hospital services, diagnostic procedures to determine the incidence and etiology, and the surgical or medical treatment of infertility are covered benefits under provincial health insurance plans (91).

Although the federal government's role in issues surrounding health care is limited, there are certain areas that do fall under federal jurisdiction. For example, the government has the authority to regulate medical devices and the storage of sperm. Accordingly, in 1981, an advisory committee to the Minister of National Health and Welfare recommended guidelines concerning the storage and utilization of human sperm (29). Although no federal action has been taken in response to this report, several individual provinces have either released reports or taken legislative action on various aspects of this issue.

Currently, the Protection of Life Project of the Law Reform Commission of Canada has established a working group to examine a number of issues, including embryo experimentation and novel reproductive techniques, as they relate to the legal status of the fetus. The report will be directed to federal law (e.g., criminal law) rather than those areas of law under provincial jurisdiction, and the commission will make recommendations to the federal Parliament (54).

Four provinces—Alberta (*Status of Children*) (1), British Columbia (*Ninth Report of the Royal Commission on Family and Children's Law: Artificial Insemination*) (17), Ontario (*Report on Human Artificial Reproduction and Related Matters*) (90), and Saskatchewan (*Proposals for a Human Artificial Insemination Act*) (102)—have published reports addressing reproductive technologies. Only two, Quebec and the Yukon Territory, have any legislation addressing these issues, and that legislation deals only with artificial insemination by donor.

Of the provincial reports, the Ontario Law Reform Commission's report of 1985 is the most comprehensive (64). The other reports dealt only with artificial insemination. The Ontario Law Reform Commission made 67 specific recommendations, generally favoring noncoital reproduction "where medically necessary to circumvent the effects of infertility and genetic impairment." It recommended that these procedures be legislatively defined as the "practice of medicine." Access to them should be restricted to "stable single women and to stable men and stable women in stable marital or nonmarital unions" (90).

In 1987, the Office of the Attorney General of Ontario organized an interdepartmental committee to study artificial insemination, human embryo research, and surrogate motherhood and to review the recommendations of the Ontario Law Reform Commission report (61). There have been no decisions to date.

The Government of Quebec has a Council on the Status of Women that examines a number of topics relating to women's rights. The Council has reviewed clinical and legislative developments with regard to certain reproductive technologies, but its 1985 and 1986 series of studies made no specific recommendations for action by the Quebec Government (92,93,94,95).

Artificial Insemination

The Minister of National Health and Welfare's advisory committee on the storage and utilization of human sperm released its report in 1981. Briefly, the committee recommended that there be provincial legislation ensuring that a child conceived by donor insemination is considered the legitimate child of the mother and her consenting husband; that federal regulations govern standards for the acquisition, preservation, and importation of sperm (the committee made specific recommendations for the standards themselves); and that artificial insemination by donor be available only in facilities where guidelines are met to safeguard the donor, the recipient, and the resulting child (29).

Legislation relevant to artificial insemination exists in two Canadian provinces. In Quebec, the Civil Code provides that the child conceived by donor insemination is presumed to be the legitimate child of the consenting spouse. As of 1984, the Yukon Territory's Children's Act provides that the consenting husband or cohabitant of a woman who undergoes artificial insemination is considered the legal father of the child, and that the semen donor is not considered the legal father (90).

All four of the provincial reports published to date in Canada agreed that a child born to a married couple through artificial insemination by donor should be considered their legitimate child if both gave written consent. The British Columbia report further stated that the husband should have all rights and duties to the child, and the donor should remain anonymous (17). The Law Reform Commission of Saskatchewan actually proposed legislation to ensure the legitimacy of the child, relieve anonymous donors from obligations toward any resulting children, and provide extensive protection of the privacy of donors, recipients, and children born as a result of artificial insemination (102).

The Ontario Law Reform Commission recommended that screening for infectious and genetic diseases should be regulated by professional standards. Limits on the number of times any one donor is used should be left to the discretion of the medical profession. Donors should be paid their reasonable expenses, but no more. Anonymity of all parties should be maintained, although in the case of genetic disease the doctor should have a duty to disclose relevant information (90).

Quebec's Council on the Status of Women reported on feminist analyses of artificial insemination by donor, noting the feminist criticism of attempts to medicalize the procedure and to ban self-insemination (92,93, 94,95).

Oocyte Donation

The Ontario Law Reform Commission, in the only Canadian report to date that has considered the issue, considered oocyte donation permissible. Furthermore, the commission stated that reimbursement of reasonable costs should be allowed, and that reimbursement of ovum donors might be greater than that of sperm donors as an invasive procedure is involved (90).

In Vitro Fertilization

The federal government of Canada currently maintains a registry to keep track of children conceived by IVF (65). The Ontario Law Reform Commission considered IVF acceptable in principle, implicitly stating that it should be used for medical reasons only (134). Donation of eggs and embryos was considered acceptable (90). Quebec's Council on the Status of Women noted the feminist critique that insufficient experimentation had preceded introduction of IVF as a clinical practice (92,93,95) and that insufficient efforts have been made to guard against its use as a prelude to eugenic prenatal diagnosis (95).

The Ontario Law Reform Commission stated that preconception sex selection in the context of IVF should be discouraged but that any law prohibiting physicians from telling a couple the sex of embryos is not desirable. The Council on the Status of Women in Quebec made a stronger statement, urging that sex selection of embryos or children should be forbidden (96).

IVF is provided as an insured service in Ontario, but only at designated centers. Prince Edward Island covers IVF, with the exception of laboratory costs. Some other provinces make the service available on an uninsured basis (91).

Freezing and Storage of Human Sperm, Oocytes, and Embryos

The report of the advisory committee to the Minister of National Health and Welfare, *Storage and Utilization of Human Sperm*, stated that freezing sperm should be allowed. Concerned about the quality of frozen sperm, the committee recommended that "until regulations establishing federal standards of quality are in effect for Canada, the importation of sperm from commercial human sperm banks should be prohibited; and no new human sperm bank should be allowed to operate outside the jurisdiction of a university or other publicly owned agency" (29). The British Columbia report recommended that sperm banking be allowed only under professional and governmental surveillance (17).

The Ontario Law Reform Commission suggested that gamete banks that buy and sell sperm, ova, or embryos should operate under federal license and should extract payment from users "to defray reasonable costs, and perhaps, to provide a reasonable profit" (5). The commission recommended limiting storage to no more than 10 years, as well as permitting disposal of excess embryos.

Research on Preimplantation Embryos

Two Canadian reports consider research on human embryos. The Ontario Law Reform Commission found embryo research acceptable in principle and approved both surplus embryos and embryos created for research purposes as acceptable sources, with a time limit of 14 days after fertilization.

In 1984, the Medical Research Council of Canada's Standing Committee on Ethics in Experimentation reviewed the adequacy and currency of the council's 1978 guidelines for the protection of human subjects in research. The committee published the revised guidelines on research involving human subjects in 1987. With regard to research on human embryos, the committee recommended that at first only research "directed toward improvement of infertility management" should be allowed, using embryos up to no more than 14 to 17 days. The committee opposed the creation of embryos for research purposes. Approval of specific research proposals involving human embryos should be made by local research ethics boards (30).

Surrogate Mothers

The Ontario Law Reform Commission recommended that surrogate motherhood contracts be enforceable, but only with the prior and continuing involvement of a family law court. The commission felt that the court should supervise the screening and counseling of the surrogate and the client, review the drafting of the contract, and monitor the fee for the surrogate (134).

Quebec's Council on the Status of Women noted the feminist criticism that the practice of surrogacy threatens to destroy unified definitions of motherhood, by dividing maternity into gestational, genetic, and social components (92,93,94), and threatens to compromise the autonomy of pregnant women by encouraging contractual or governmental restrictions on their decisions concerning prenatal diagnosis and care (94,95).

Federal Republic of Germany

No national organization in West Germany regularly considers biomedical developments and ethical or political responses (103). Nor do hospitals have ethics committees or institutional review boards, unless they are teaching or research hospitals (104). However, a number of private and governmental committees are considering guidelines for noncoital reproduction and embryo research. These include the Bundesärztekammer's Wissenschaftlicher Beirat (Scientific Council of the German Medical Association), which issued guidelines for professional standards on IVF and embryo research (13,19,103). During their annual conventions in 1970 and 1985, West German physicians passed resolutions concerning artificial insemination and IVF, and subsequently issued guidelines related to IVF (24). Membership in the organization is obligatory for any practicing physician, and the association has a greater ability to dictate policy and enforce its guidelines than does any American association (67).

Another active group has been the Bundesministerium für Forschung und Technologie (Federal Ministry for Research and Technology), which initiated discussion of ethical implications of biotechnology (51,103), as well as collaborated with the Ministry of Justice to consider restrictions on noncoital reproduction (50). Their joint report, known as the Benda Report, was completed in 1985 and recommended numerous restrictions on the use of noncoital reproductive techniques.

In 1987, an ad hoc commission to the German Parliament (known as the Enquete Commission) delivered a report on biotechnology that recommended the acceptance of reproductive and genetic technology subject to strong legal regulation (52,67). Also in 1987, the Federal-State Working Group on Reproductive Medicine published an interim report, which is more liberal in its proscriptions (48). This committee, consisting of representatives of the justice and health ministries of the federal government and of the states, was created by mandate of the upper house of the German Parliament, and its report is expected to gather wide political support (57). No action has been taken yet on either report, although draft bills concerning surrogacy and embryo management are now under consideration by various ministries (57).

Artificial Insemination

In their resolution of 1970, the German Medical Association stated that donor insemination is not contrary to professional ethics, but that it is so beset with difficulties that they could not recommend the procedure (24). The Benda Report also expressed strong reservations about its use, noting concern about releasing the genetic father from responsibility for his child; about selecting donors, both in terms of having a third party select the father of a child and the possibility of eugenic considerations playing a role; and about any inbreeding that might result.

There is no statute in West Germany pertaining to the legitimacy of a child conceived by donor insemination, but two cases in 1982 and 1985 addressed the question. Under German law, any husband has the right to contest paternity, within a specified period of time. If successful, the child's genetic father (even if an anonymous sperm donor) may become legally responsible. The 1982 case allowed a paternity challenge when a husband objected that the child his wife had borne was conceived by extramarital intercourse rather than by the artificial insemination attempts that had been ongoing during this period.

A 1985 decision, on the other hand, ruled that if a man has agreed to his wife's use of donor semen and has renounced his right to contest paternity, he may not later challenge the legitimacy and paternity of the resulting child, despite the fact that he was now leaving the marriage and joining another woman. At least one commentator applauded the latter decision, noting that it is always possible to be certain of the paternity of a child, and that artificial insemination practice would become untenable if men could routinely present postbirth objections to the paternity of a child, despite their earlier agreement (81).

The Benda Report recommended that a child conceived by donor insemination should have free access to the details of his or her parentage, stating that the personal details of the donor be recorded and made available to the child produced when he or she turns 16. Similar recommendations were made in a 1986 report by the national legal association (42). This, coupled with sperm donors' fears of future responsibility toward the children, has made donor insemination rather uncommon (103).

The Benda Report recommended that one sperm donor be used for no more than 10 births. Beyond this it did not comment on screening sperm. As the German Medical Association, fearing commercial misuse and involuntary incestual relationships, had previously recommended that donor semen not be used, the Benda Report generally did not address regulation of semen donation, for the practice would probably not be used extensively.

The report of the federal-state working group addressed artificial insemination by husband and by donor separately. The report specified that insemination by a woman's partner should be available to married or unmarried couples, but only if medically indicated. The written permission of the husband or partner should be required, and sex selection and postmortem insemination should be forbidden (48).

The working group recommended that donor insemination be available only when the male has otherwise untreatable infertility. It should not be available to unmarried couples or single women. Consultation by a doctor should be required. The husband must be a voluntary participant, as indicated by a notary deed stating his intention to accept paternity. The man thus loses his right to renounce his consent to the procedure; he cannot regain this right unless he obtains another notary deed. All claims for support and inheritance between the donor and the resulting child should be excluded, but a petition for a declaration of fatherhood without these financial effects should be possible.

As the working group, unlike the Benda commission, did consider donor insemination a potentially widespread practice, their report addresses regulation of semen donation. The recommendations state that one donor should not be used for more than one live birth, and mixing sperm should be forbidden. There should be a central register of donor data that remains confidential, but the possibility of allowing the child to learn his or her genetic heritage should remain open. Doctors should be allowed to screen donors for health and similarity to the recipient's husband only, and payment of donors should be forbidden. Donor semen should be screened before insemination and should not be transferred from doctor to doctor. The use of a deceased donor's sperm is forbidden (48).

Oocyte Donation

Current legislation in West Germany does not cover egg donation. The Benda Report recommended that the woman who gives birth, rather than the genetic mother, be initially regarded as the lawful mother, just as the husband of an artificially inseminated woman should initially be considered the lawful father. The birth mother may not have any grounds to contest legitimacy, as she has contributed substantially to the birth by carrying the fetus. The legal position on this point is unclear.

As with artificial insemination by donor, the Benda Report did not address regulation of egg donation, as the medical establishment does not condone the procedure. However, it maintained that the child resulting from ovum donation should have free access to the details concerning his or her genetic mother.

Like the medical establishment, the federal-state working group did not approve oocyte donation. However, the report did state that civil law should recognize the birth mother as the legal mother of any child (48).

In Vitro Fertilization

The resolution of the 1985 physicians' convention concerning IVF stated that guidelines should ensure the high medical quality of IVF facilities and personnel and that, in principle, IVF should only be offered to married couples using their own sperm and eggs. Exceptions are possible only after approval by a commission established by the German Medical Association (44). Since the publication of the Benda Report, the German Medical Association's statements have tended to be more restrictive, insisting that IVF be strictly limited to married couples using their own gametes (67). Guidelines concerning the conditions under which IVF and embryo transfer should be carried out have also been issued by the organization (18,24).

The Benda Report recommended that legislation be enacted restricting the use of IVF techniques to medical establishments that satisfy certain safety requirements to be specified by law. Although it considered nationwide legislation desirable, it recognized that the federal legislature may not have the constitutional authority to pass the legislative measures called for, and thus they recommended to the representative body of the German states (the Länder) that they work out regulations free of inconsistencies. The medical profession opposes legislation, insisting on the sufficiency of self-regulation (67,103,104).

According to the Benda Report, the genetic parents of an embryo created in vitro have a limited right to determine the use or disposal of the embryo. If, in the course of treatment, embryos are created that cannot, for whatever reason, be transferred, a mother cannot be forced to allow implantation into another woman to ensure that the embryo develops. Embryo donation is only justified when it is voluntary, it allows an embryo to develop, and a married couple is willing to accept the child as their own.

The Benda Report also approved IVF using the husband's sperm as a means of treating sterility. IVF should in principle be offered only to married couples. Only in exceptional cases should cohabiting couples be offered IVF, and the procedure should not be offered to single persons. The resulting child, if the procedure were allowed in these cases, would be illegitimate. A child resulting from embryo donation to a married couple is legitimate under the section of the German Civil Code that states that a child born in the course of a marriage is always regarded as legitimate, although the law at present makes no special provision in this case. The question of the right to dispute legitimacy is particularly complicated in the case of embryo donation, as both parents might have grounds for dispute.

The federal-state working group recommended that IVF be available to married couples using their own gametes and only when medically indicated. The physician must perform a comprehensive medical and psychological exam, which must be documented. Doctors should only fertilize as many eggs as can be transferred at that time, and donation of superfluous IVF embryos or embryos flushed from a woman's body should be forbidden. Finally, the report addresses gamete intrafallopian transfer, stating that it should be subject to the same regulations as IVF (48).

Freezing and Storage of Human Sperm, Oocytes, and Embryos

Freezing embryos and sperm troubled members of the Benda Commission, who feared that a person conceived by such techniques might become confused about his or her identity; family relationships, for example, might be confused if gametes are frozen for an extended period of time and then allowed to develop.

Thus the Benda Report states that cryopreservation of human embryos can only be considered when embryo transfer is not possible for some time and cryopreservation provides an opportunity for transfer within the next 2 years, or when the embryo is to be transferred during one of the woman's following cycles in order to improve the embryo's prospect of implantation. The German Medical Association similarly states in its guidelines that cryopreservation for a limited time is permitted if it improves the embryo's chances for implantation or represents a temporary measure until another opportunity for transfer arises (24).

The federal-state working group recommended that the cryopreservation of sperm and oocytes occur only in officially regulated facilities and be limited to 2 years. The freezing of embryos and fertilized eggs should be forbidden except when the woman's condition does not permit transfer at the time and she desires cryopreservation (48).

Research on Preimplantation Embryos

The majority view presented in the Benda Report stated that, as a matter of principle, creating human embryos for research, without intending to implant them, cannot be justified. Experiments with human embryos are justifiable only if they assist in diagnosing, preventing, or curing a disease that the embryo in question is suffering from or if they "help to obtain specific medical findings of great value" and are reviewed by both a local and a central ethics committee (50). Consistent with this was the 1985 German Medical Association resolution stating that "embryos produced in vitro must, on principle, be implanted as part of the particular infertility treatment being carried out. Experiments with embryos must, on principle, be rejected insofar as they do not serve the improvement of clinical method or the well-being of the child" (24).

Embryo research was also identified in the joint Ministry of Justice and Ministry of Research and Technology report as harmful to human dignity (50,103), and the Ministry of Justice followed up on the report by drafting restrictive legislation (49). The Ministry of Justice draft proposed penalties of up to 5 years imprisonment for engaging in embryo research without permission of the genetic parents, especially if severe damage or loss of embryos ensues. Also penalized would be performing IVF without an intent to implant the resulting embryos, maintaining in vitro embryos beyond the normal point of implantation, artificially maintaining nonviable embryos, creating chimeras, or cloning (49,103). Resistance to this particular proposal has been vehement, particularly from the German Medical Association and research funding organizations (57,67,103). Commentators note the inconsistency between German law allowing abortion during the first trimester and the near total ban on embryo research during that same period (103).

The federal-state working group report, published after the draft legislation, also stated that creating embryos or fertilized eggs for research purposes should be a criminal offense. Research on superfluous embryos should be forbidden, as should altering the genetic makeup of an individual, splitting embryos, creating chimeras or hybrids, and cloning (48).

Surrogate Mothers

Any commitment a woman makes to carry a child for another couple is legally unenforceable in Germany. Two German courts dealt with surrogate contracts in 1985. One determined that the child's custody could not be supplanted by a prebirth agreement by the mother to give up custody, and the other ruled that the contract was void (47).

The Benda Report opposed any form of surrogacy, and furthermore interpreted surrogacy as unconstitutional, as it fails to respect the dignity of the child. Participants at the 1985 convention of physicians also opposed any form of surrogacy, stating in a resolution that "in view of the possible disadvantages for the child, and given the danger of in vitro fertilization and embryo transfer being commercialized, recourse to the services of 'surrogate mothers' must be rejected" (50).

The national legal organization recommended in 1986 that ordinary surrogacy, i.e., where the surrogate is the genetic and gestational mother of the child, is not inherently immoral, but that the legislature nevertheless could and should outlaw the practice (42). With regard to gestational surrogacy, the association went further, stating "it does not take into account that the development in the uterus is part of the personal development of the child and violates the human dignity of the female who has been made an instrument . . ." (104).

The federal-state working group recommended in 1987 that medical participation in surrogacy be foridden, that contracts for surrogacy be unenforceable, and that commercial surrogacy and advertisement be forbidden (48).

Recently, a U.S. commercial surrogate motherhood agency opened an office in Frankfurt to match West Germans with American surrogates. The magistrate of Frankfurt announced that the agency must be closed, if necessary by compulsary measures, but the agency refused (132). The conflict went to the courts, and in early 1988 a West German state court ruled that the agency must close as it violated West Germany's adoption laws (6).

France

The French national debate on the use of noncoital reproductive technologies is still quite lively. In 1986, the Comité Consultatif National d'Ethique (CCNE) held public hearings in Paris and Lyons (34), to follow up on its previous work (33). The CCNE has no legal authority. Its initial purpose was to pave the way for subsequent legislation, but nothing has followed thus far (71). The Ministry of Justice prepared a 30-country review of regulatory and ethical developments with respect to all forms of medically assisted reproduction (24), and the Conseil d'Etat is preparing a report to the Prime Minister dealing with the need for statutes in this field (23).

Since 1978, the French Public Health Code has provided regulations requiring the funding of artificial insemination and IVF by the National Health Service (23).

Artificial Insemination

Ninety percent of artificial insemination by donor recipients in France order their sperm from one of France's 23 sperm banks, called the centers for the study and preservation of semen (CECOS). Policies governing artificial insemination by donor are thus mostly designed by the physicians running CECOS after a discussion in a CECOS National Commission, and the restrictions are quite rigid. Other institutions and private practices have more flexible rules (89).

The CECOS have developed an artificial insemination by donor program with the Statistical Research Unit of the National Institute of Health and Medical Research (INSERM). The established regulations require that sperm donors be married and of proven fertility and that the donor's wife give her permission for the procedure. Donors are screened for sexually transmitted diseases (including acquired immunodeficiency syndrome) and genetic problems, and karyotypes are routinely performed. Semen is provided only to stable couples, and only if the male partner is sterile or carries a hereditary disorder (2). Donors are anonymous and unpaid, and donor semen is available at no cost to infertile couples in France.

In one case regarding artificial insemination by husband, a French widow was successful in her suit to obtain her late husband's sperm in order to bear his posthumous child. Her attorney argued that "a deceased man has the right to breath life into the womb of his wife and prove that love is stronger than death" (74). The court did not consider the sperm as property. Its reasoning was based on the fact that the widow proved that her husband stored his sperm with the strong desire to beget a child by her (23).

In Vitro Fertilization

Over 100 IVF centers existed in France as of December 1985 (2). Quality of practice, restrictions on eligibility, and profitability vary enormously. Only a certain number follow the suggestions of CCNE, which recommended that centers be nonprofit and that a central organization be designed to pass on questions of gamete donation. However, legislation has been introduced that would restrict IVF to a limited number of centers that will be licensed only if they conform to strict technical requirements (53). Although IVF does not usually require egg or embryo donations, a few large and experienced centers do provide this service

(46). The CCNE recommended that legal rules be developed before embryo donation be allowed (22). An independent society named FIV-NAT has been created to centralize data concerning IVF (32).

Freezing and Storage of Human Sperm and Embryos

From the beginning, the CECOS have always frozen sperm because insemination is done outside the hospitals by a local gynecologist. CCNE considers embryo freezing an experimental procedure that should be performed only under strict conditions (for example, the first implantation should occur after no longer than 6 months and excess embryos should not be kept more than 1 year) (23), but the majority of CECOS do perform embryo freezing. Cryopreservation is now being performed in many centers not related to the CECOS as well (32).

Research on Preimplantation Embryos

After CCNE was created in 1983, it established several working groups that published reports on issues related to noncoital reproductive techniques. In 1986, CCNE published a long report on the ethical acceptability of research on human embryos, recommending that embryos not be created for research purposes, that IVF be carried out only in centers approved by public authorities, and that research aimed at making a genetic diagnosis prior to implantation undergo a 3-year moratorium (34,46). In spite of the dissenting opinion of some members, CCNE did not forbid all research on in vitro embryos, provided that embryos are not kept beyond 7 days. Furthermore, the committee did not forbid the use of surplus embryos for research (23).

Surrogate Mothers

Surrogacy contracts appear to be unenforceable because of a French adoption law prohibiting baby-selling. In addition, under French law, agencies and individuals who use the agencies' services to effect surrogate parenting arrangements are subject to prosecution. The Ministry of Health dissolved the three agencies facilitating commercial surrogacy agreements and they are now illegal (32).

Israel

General laws in Israel are secular and are legislated by the Knesset (the Israeli Parliament); matters concerning marriage, divorce, paternity, legitimacy, and bastardy are adjudicated according to the Jewish religious laws as determined by the Rabbinical courts. The practice of the new reproductive technologies thus must be supported by religious authorities (106). Although large sectors of the Israeli population will be guided by religious laws concerning the new reproductive technologies, this section will deal exclusively with the Government regulations. Religious views concerning these technologies, which sometimes differ from but do not necessarily conflict with secular laws, are covered in appendix F.

In 1980, the Director General of the Ministry of Health promulgated Public Health Regulations (Human Experimentation), 1980, in an effort to devise a supervisory mechanism in the field of biomedical research involving human subjects. These regulations state that medical experiments on humans, may only be conducted in a hospital if authorized by the Director General and if in accord with the provisions of the Regulations and of the Helsinki Declaration on Human Rights. Before the Director General can authorize a medical experiment involving humans, it must be approved by what in Israel is called a Helsinki Committee, and the Director General must obtain an opinion from the Drugs and Food Administration of the Ministry of Health or from the Supreme Helsinki Committee for Medical Experiments on Humans. One of the areas for which the Supreme Helsinki Committee is responsible is experiments involving the artificial fertilization of a woman (108).

From 1981 to 1987 the Knesset did not enact legislation to deal with many matters concerned with artificial reproduction (106). However, the Ministry of Health attempted to regulate these issues by means of secondary legislation. The Director General of the Ministry of Health sent a circular to all hospital directors spelling out rules for the regulation of sperm banks and artificial insemination. The legal authority for promulgating this secondary legislation was tenuous (110). In 1986 the Ministry of Health published draft regulations dealing with various aspects of artificial reproduction. The Supreme Helsinki Committee discussed these regulations a month later, offering several revisions. The draft was revised and the formal declaration of the regulations was made in 1987 (109).

In 1987, the Knesset approved the Ministry of Health's new Public Health (Extracorporeal Fertilization) Regulations (60), which adopted the 1979 regulations on artificial insemination, and adopted new regulations concerning IVF and ovum donation. The 1987 regulations continue to ban surrogacy in any form.

Artificial Insemination

The Ministry of Health regulations pertaining to artificial insemination by donor were signed in 1979 and readopted under the 1987 regulations. They state that artificial insemination by donor may only be performed by a licensed obstetrician or gynecologist after examination of both the wife and the husband, (72).

According to the regulations, only a doctor may choose the sperm to be used in donor insemination. The blood type of the donor must have the same Rh factor as that of the husband, and the number of times that a donor may donate sperm is limited (72). The donor must have a medical examination and be free of certain ailments and of exposure to the human immunodeficiency virus (107,109). Mixing of the donor's sperm and the husband's sperm is to be done as much as possible (108), and Regulation 15 states that the donor shall remain anonymous (60).

The regulations dictate that strict records must be kept of both the sperm donor (to regulate how many times one man donates) and the sperm itself (to record specifics such as blood type, skin color, hair color, and Rh factor, but not the personal identity of the donor). However, access to these records in sperm banks is strictly limited, and the identity of the donor and of the wife and husband may not be revealed to anyone, including the parties themselves. The written consent of both the husband and the wife are required (108).

The regulations also state that the sperm donor is required to give his written consent to the use of his sperm for the purpose of artificial insemination. Presumably in doing so he gives up all rights and duties to the child. The regulations further state that the husband should declare that the child will be considered his own natural child for all purposes (108).

In Jewish law, there is controversy over whether a child conceived by donor insemination is illegitimate. Secular law does not directly address the issue of legitimacy, but as a secular system will probably consider the welfare of the child to be the most important consideration, a child conceived by donor insemination is probably considered legitimate (110).

In 1979, the Israeli Supreme Court had its first encounter with artificial insemination when a man refused to pay support for a child born to his wife after donor insemination. The court dismissed his contention that he had not agreed to the artificial insemination, and thus ruled that he must pay, whether divorced or not. Because the Supreme Court recognized the agreement, it may be assumed that it does not condemn artificial insemination by donor, at least when a woman is married and her husband consents (110).

Oocyte Donation

The Supreme Helsinki Committee and the regulations of the Ministry of Health both state that ova may be recovered for purposes of donation only from women themselves undergoing infertility treatment and during the course of such treatment. In other words, women may not undergo the invasive procedure necessary to retrieve eggs simply for the purpose of donating them to another or for donating them to a laboratory (60). The Supreme Helsinki Committee recommends that an egg donor should be limited to donating to one recipient (108), and, as with sperm donation, the egg donor should remain anonymous, with all her rights and obligations to the child cut off under Regulation 15. Oocyte cryopreservation is permitted, and post-mortem donation of an egg is permitted if the genetic mother was single and if she left written evidence of permission.

Only married women intending to raise the resulting child may accept donated eggs, thus ruling out gestational surrogacy. The recipient also may not be related to the egg donor. Related, under Regulation 12, includes parent, child, grandparent, sibling, aunt, or first cousin. Women accepting a donated egg must use their husband's sperm for fertilization, as contrasted with those receiving IVF using their own eggs, in which case donor sperm may be substituted. The net result is that a couple cannot gestate and rear a child to whom neither parent is genetically related. Upon birth of the child, the recipient of a donated ovum must take steps to formally adopt the child, thus implying that under Israeli law, maternity will follow the paternity model, and will be based upon genetic rather than gestational connection.

The Ministry of Health regulations recommend that a woman only receive an ovum from someone of the same national origin. This restriction derives from the traditional Jewish religious law that states that a Jew is someone born to a Jewish mother. Recognizing that a child resulting from the implantation of an ovum from a non-Jewish woman in a Jewish woman could create considerable inconvenience for the child, who might not be considered Jewish, the regulations suggest that ovum donation not be made across religious or national differences, but do not prohibit the practice (108).

In Vitro Fertilization

Regulation 4 permits IVF only if a woman is infertile and her physician recommends the procedure (107, 109). Regulation 8 further states that single women may be eligible for IVF, provided that a social worker certifies that the woman is psychologically and economically capable of raising a child (60). Retrieval and donation of ova and freezing and implantation of fertilized eggs are permitted only in a hospital authorized by the Director General of the Health Ministry to carry out these procedures. Authorization is granted after inspection for the adequacy of personnel, clinical and laboratory equipment, recordkeeping, and attention to ethical problems, and authorization may be revoked if the standards do not continue to be met.

Both members of the couple undergoing IVF (or the woman, if she is single) must give written consent to the procedure. Donor sperm may be used, provided that the woman is using her own egg. Single women must use their own eggs, as egg donation to single women is not permitted.

Freezing of fertilized eggs is permitted, but is limited to a period of 5 years, unless special consent is obtained to extend that period to 10 years (60,107,109). A frozen fertilized ovum may not be implanted in a woman in the following instances: if the woman is divorced and the egg was fertilized by her former husband's sperm, unless the latter consents to the implantation; if both genetic parents are dead; or if the woman is a widow, except when a year has already elapsed since her husband's death and a written report has been made by a hospital's social worker that the widow is psychologically and economically capable of raising a child (60). No use may be made of a frozen fertilized egg if its genetic mother has died.

Research on Preimplantation Embryos

The 1987 regulations permit egg retrieval only for the purpose of fertilization and implantation. This may operate as a ban on experimentation with embryos, as no embryo may be deliberately formed for the purpose of experimentation. It is not clear, however, whether the genetic parents of a frozen embryo may donate it to a laboratory for experimentation purposes if they no longer wish to try implantation and gestation for themselves.

Surrogate Mothers

After the practice of IVF became established and egg donation received a qualified endorsement, the Supreme Helsinki Committee was asked to approve IVF with subsequent embryo transfer to a "host," or gestational, mother. However, the Committee dismissed surrogacy. The regulations of the Ministry of Health also ban implantation of a fertilized egg in a woman not planning to be the child's mother (60).

After studying the issue of surrogacy for a considerable amount of time, the Health Minister and Attorney General decided to publish regulations that would outlaw the practice of surrogacy in Israel (4).

South Africa

In 1986, pursuant to the Human Tissues Act of 1983 and the recommendations of a working committee (113), South Africa's Department of National Health and Population Development issued regulations governing the physician licensing and gamete donation associated with IVF and artificial insemination (112).

Artificial Insemination

The 1986 regulations specify that artificial insemination by donor may only be performed by a physician who has been registered and approved by the Director General of the Department of National Health and Population Development. Physicians must maintain detailed records of each donor and recipient, of the transfer of gametes, and of the health of the children born by donor insemination. These records form the basis of an annual report to the Director-General, who maintains a central registry of gamete donation, and help to ensure strict compliance with the limit of five children per donor. If the physician does not attend the birth of the child, the mother must within 30 days of the birth report on the health of the child. Any evidence of a hereditary disorder must be followed by an inquiry into the mother's and donor's genetic health.

The regulations require that a donor be screened for sexually transmitted diseases, fertility, and general health. The records maintained, to which the recipient may have access, note the donor's age, height, weight, eye and hair color, complexion, "population group," nationality, religion, occupation, education, and interests. The donor's spouse must agree to the use of his sperm for donor insemination, and the donor may limit the use of his sperm to recipients of specified religion and population groups.

Donor insemination is available only to married women. Recipients are screened for all of the same conditions as the donor, as well as to ensure that they are "biologically, physically, socially, and mentally suited for artificial insemination." Records are maintained with "particular reference to possible genetic conditions and mental disorders." Recipients and their husbands must be advised by the physician of the psychological and legal risks of donor insemination, and must receive counseling if the recipient appears to be a carrier for any heritable disorders.

The 1986 regulations do not address the legal status of the resulting child. In 1979 a South African court ruled that a child conceived by donor insemination was illegitimate. The judge, however, did not declare the procedure unlawful or ethically undesirable, and urged the legislature to legitimize children conceived by donor insemination (118).

Oocyte Donation

Oocyte donation is allowed in South Africa, and screening of the donor and recipients is subject to precisely the same provisions as screening for donor insemination.

In Vitro Fertilization

The 1986 regulations do not address IVF except with regard to licensing physicians and regulating the use of donor gametes. The working committee did, however, consider a number of additional points. Most members of the working committee whose recommendations formed the basis of the 1986 regulations had no fundamental objections to IVF. They approved IVF with the gametes of the infertile couple as well as with donor gametes or donor embryos.

According to the 1986 regulations, IVF may only be performed on licensed premises by registered gynecologists and these facilities must be centralized and their number restricted. Later implantation for the same couple was acceptable to the majority of the committee and, as far as is known, to the majority of the community as well. The committee stated that embryos may be donated to other infertile couples only if the second infertile couple cannot overcome the infertility in any other way or may transmit serious hereditary disorders. Donated gametes may not be used unless each donor has given explicit written consent for the use of their gametes to form an embryo. When an embryo has been donated, it must be used for the selected participants.

Research on Preimplantation Embryos

The committee stated that research on preimplantation embryos should be allowed under strict conditions approved by the responsible research-controlling body for a period up to 14 days after fertilization. The committee further concluded that embryo flushing is still an experimental procedure and thus it should not at present be part of an IVF program.

Freezing and Storage of Human Sperm, Oocytes, and Embryos

The committee recognized the benefits of embryo freezing for an IVF program, and suggested that the participants in the program should be able to indicate how they want excess embryos handled. Freezing and storage of human embryos is allowed with the consent of the participants of the IVF program or the donors of the gametes used to form the embryo. A bank of frozen embryos is not to be allowed; each frozen embryo must be retained for participants, and if donated must be used for the selected participants.

Donors must consent to freezing and storage of an embryo formed from their gametes. Furthermore, donors may decide the manner in which a stored embryo is to be used—whether it is to be donated to other participants in the IVF program, whether it can be made available for research, or whether storage is to cease. Conditions governing use of the embryos shall be incorporated as part of the consent document.

Surrogate Mothers

The working committee considered commercial surrogacy ethically unacceptable. It stated that surrogacy contracts are unenforceable and that volunteer surrogacy should not be included in the IVF program. The medical profession in South Africa also opposes surrogate motherhood. The Medical Association of South Africa declared it "undesirable," and the head of the country's leading IVF laboratory has also expressed disapproval (16).

One unusual surrogate motherhood case has drawn international attention to South Africa. In 1987, a 48-year-old grandmother bore triplets conceived in vitro from her daughter's ova and her son-in-law's sperm (45). Experts disagree on the legal status of the children; one law professor said that the daughter might have to adopt the children to protect her rights, while another claimed that since the surrogacy was not part of a commercial arrangement there should be no legal problems for the family. A third stated that under common law the children will be legitimate, as they were conceived with the gametes of a married couple (16).

Sweden

In 1981, the Swedish Government formed a committee that is currently investigating most of the issues surrounding noncoital reproductive techniques. The Insemination Committee has published two reports, one in 1983 concerning artificial insemination (121) and one in 1985 concerning IVF and surrogate motherhood (122). Some of the recommendations of the 1983 report became law in March 1985.

Artificial Insemination

Artificial insemination, both by husband and by donor, has been carried out in Sweden since the 1920s.

In 1983, the Government committee published *Children Conceived by Artificial Insemination*. This report stated that there is "no specific protection for the AID [artificial insemination by donor] child, judicially or in any other respect" (121). The committee's general point of departure was therefore "that the needs and interests of the prospective child be satisfied and safeguarded in a satisfactory way." The committee found "strong reasons in favor of drawing parallels between adoption and AID" (121).

These recommendations resulted in a 1985 artificial insemination law (119). According to this law only women married or cohabiting with a man under circumstances of marital character should be allowed insemination treatment; insemination requires a written consent by the husband or cohabitant, who will, by this act, be regarded as the legal father of the child born following the treatment; artificial insemination by donor should only be undertaken in general hospitals under the supervision of a physician specialized in obstetrics and gynecology, and the sperm donor should be chosen by the physician; information about the donor of sperm should be kept in a special hospital record for at least 70 years; when a child conceived by donor insemination is mature enough, he or she has a right to obtain information about the identity of the natural father, information that is kept in the special hospital record; and, when requested, the public welfare committee is duty bound to assist the child in retrieving this information (119). The question of contact between the donor and child is not regulated. The National Board of Health and Welfare has stated that such contacts sometimes can be of great value to the child, but must be voluntary on all sides. The parents are not obligated to tell the child of the use of donor insemination for his or her conception, but are encouraged by the board to do so (58,66).

The physician performing artificial insemination by donor should examine the suitability of the technique with respect to the medical, psychological, and social circumstances of the prospective parents. Finally, the insemination should only be undertaken if the circumstances of the prospective parents are of a character enabling the child to grow up under favorable conditions (119).

Oocyte Donation

The Government committee recommended that egg donation be prohibited in Sweden (122).

In Vitro Fertilization

IVF is not regulated in Sweden, although legislative work is in progress (73). The Government committee proposed that IVF treatment be restricted to women married or cohabiting under marital circumstances, that the implantation of the fertilized egg requires a written consent by the husband or cohabitant, and that without the permission of the National Board of Health and Welfare, IVF may only be undertaken in general hospitals. Regarding donor gametes in IVF, the committee further suggested that an in vitro fertilized egg should only be implanted in the woman from whom the ovum was recovered and that the egg should only be fertilized by the semen of the husband or cohabitant (122).

Research on Preimplantation Embryos

In 1982 the Swedish Government appointed a different committee to study the ethical, humanitarian, and social issues arising from the use of genetic engineering. The Committee on Genetic Integrity published a report, *Genetisk Integritet* (Genetic Integrity), in 1984 (120). It did not propose a limit on human embryo experimentation but instead suggested a number of ethical norms to be followed. Regarding research on embryos, the committee recommended that "research and experiments on zygots and embryos are acceptable provided they are medically well-founded, that they are performed within 14 days after fertilization (freezing time not counted), and that the donor of eggs and sperm has given her/his free and informed consent" and that "human zygots and embryos exposed to experiments must not be implanted and developed *in vivo*" (120). They further recommended that any experiments proposing to violate these guidelines must come under severe ethical examination. Legislative work on this issue has not been completed (73).

Surrogate Mothers

The Insemination Committee regarded surrogate motherhood as indefensible due to the risk of children becoming objects of financial bargaining. The procedure would require extensive changes within the legal system, which the committee saw no reason to consider (122).

United Kingdom

In 1984, the Government-sponsored Warnock Committee (named after its chairperson, Dame Mary Warnock) made 63 specific recommendations concerning noncoital reproductive techniques and reproductive research (125). The Warnock report has been influential in the United Kingdom and elsewhere, as it was one of the first national committees to address the ethical, legal, and social implications of the new reproductive technologies (64). The ethical and social deliberations have been discussed in chapter 11; this section covers the legal issues.

The Government's first response to the Warnock Report was to introduce legislation in 1985 banning commercial surrogacy. Regarding other issues surrounding infertility treatment, the Government decided further consultation was needed. Thus, in 1986, the Department of Health and Social Security released a Consultation Paper, *Legislation on Human Infertility Services and Embryo Research* (126). The document encouraged further discussion on the following questions: the need for a statutory licensing authority for infertility treatment, the need to counsel infertile couples, the legal status of children resulting from techniques that use donated gametes, the definition of mother and father in cases of egg or embryo donation, the enforceability of surrogacy contracts, storage and disposal of human embryos, and research on human embryos (126).

The consultation period ended in June 1987, and in November 1987 the Government issued a White Paper that should be the basis for future regulation (127). The proposals generally followed the recommendations of the report, unless otherwise noted. The most notable deviation is the presence of alternative clauses on embryo research; the Government is leaving this decision to free vote by the Members of Parliament.

The Warnock Committee recommended that a statutory licensing authority be established to regulate certain infertility services and related research. As an interim measure, the Medical Research Council and the Royal College of Obstetricians and Gynaecologists formed a Voluntary Licencing Authority (VLA) to regulate the clinical practice of IVF and embryology. The guidelines published in the VLA's first two reports are consistent with the recommendations made by the Warnock Committee (130,131). The Government's White Paper of 1987 then proposed a Statutory Licencing Authority (SLA) that would oversee the following areas: any treatment (or research, if approved) involving human embryos created in vitro or taken from the womb of a woman (e.g., by lavage); treatments involving donated gametes or donated embryos; the storage of human gametes or embryos for later use (by cryopreservation); and the use of diagnostic tests involving fertilization of an animal ovum by human sperm. The SLA will be responsible, among other items, for licensing and collecting data on facilities offering these techniques. The White Paper states that the use of these techniques without the appropriate license is a criminal offense.

Artificial Insemination

Section 27 of the Family Law Reform Act 1987 follows the Warnock recommendation that a child conceived with donor semen is the legitimate child of the mother and her husband, provided both have consented to the procedure. The White Paper states that legislation will establish that the sperm donor will have no parental rights or duties to the child.

The White Paper proposes that the SLA keep a central record of all gamete and embryo donations and births resulting from these donations. All adults over the age of 18 conceived by gamete or embryo donation should have a legal right to find out how they were conceived and to obtain certain nonidentifying information about the donor. The Government plans to construct the bill so that this provision can be amended and the possibility of granting access to identifying information remain open. This measure would be made retroactive.

Although the White Paper recognized that limiting the number of donations from any one donor is desirable, it did not propose stating a limit within future legislation. Instead, it proposed that the SLA set and regulate this limit. It also stated that the SLA will be responsible for making sure that any financial transactions are for the recovery of reasonable costs only.

Oocyte Donation

The White Paper proposes that the provisions of section 27 of the Family Law Reform Act 1987 be extended to children born following egg and embryo donation, so that any child born to a couple using donated gametes or a donated embryo be considered the legitimate child of that couple, provided the husband and wife both consented. The White Paper also states that legislation will make clear that where a child is conceived with donated gametes or embryos, the birth mother shall be regarded in law as the child's mother. Furthermore, the donor(s) will have no parental rights or duties to the child.

In Vitro Fertilization

The Warnock Committee proposed that IVF be available to all couples, whether married or not, but the Government White Paper did not specifically mention whether marriage should be a prerequisite. According to the White Paper, artificial insemination by husband or by donor, egg donation, and embryo donation in conjunction with IVF should continue to be available, subject to the recommended licensing and inspection. The Warnock Committee did not recommend the use of embryo donation by lavage because the technique was not known to be safe, and the White Paper fails to specifically mention this technique.

The guidelines published in the VLA report state that clinical and research facilities carrying out IVF must have access to an ethics committee, keep detailed records, and have appropriately trained staff. No more than three embryos, or four in exceptional circumstances, should be transferred to a woman (129). The VLA visited IVF centers and evaluated them; 30 IVF clinics had been approved and licensed by the VLA as of 1987 (131).

The proposed SLA will similarly oversee facilities offering the regulated infertility treatments. The White Paper states that the SLA will ensure there is adequate staffing, quality facilities, recordkeeping, screening and assessment procedures, and arrangements for storage and disposal of gametes and embryos.

Freezing and Storage of Human Sperm, Oocytes, and Embryos

Although the Warnock Committee considered freezing sperm acceptable, it stated that freezing oocytes would be acceptable only if the technology improved. Embryo cryopreservation was considered acceptable as an experimental technique.

The White Paper stated that cryopreservation of human gametes and embryos should be permitted, but only under license from the SLA and subject to certain conditions regarding maximum storage times. According to the Government, gametes may be stored for a maximum of 10 years, while embryos may be stored for a maximum of 5 years.

The White Paper also states that storage of gametes and embryos can only take place with the written consent of donors. The donor's wishes should be followed during the period during which embryos or gametes may be stored; when this period expires, they may be used by the licensed storage facility for other purposes only if the donor gave consent for such use. Concerning embryos, all possible uses (implantation into another women, research, destruction) must be approved by both donors. If disagreement exists, the embryo must be left in storage until the end of the storage period, then discarded.

Research on Preimplantation Embryos

The majority of the Warnock Committee members recommended that research on embryos be allowed for up to 14 days after fertilization but only under license, and whenever possible with the informed consent of the couple from whom the embryo was generated. (Nine of the sixteen members recommended this course of action; three were opposed to all experimentation on embryos; and four were opposed to experimentation on embryos created solely for the purpose of research.) The current VLA guidelines follow the committee's suggestions, allowing research on embryos up to 14 days with the consent of both donors only if the information needed cannot be obtained by research on other species.

There has been considerable controversy in the United Kingdom concerning embryo research. Three bills were introduced by members of Parliament to ban such research, all of which have been defeated. The British Medical Association, the Royal College of Obstetricians and Gynaecologists, and the Medical Research Council all favor carefully regulated research on early embryos (55).

The Government White Paper did not follow the recommendations of the Warnock Committee on this issue; it proposed alternative draft clauses to be voted on by Members of Parliament. One clause forbids any research on human embryos not aimed at preparing the embryo for transfer to the uterus of a woman; the other permits any project specifically licensed by the SLA. Regardless of which clause is used, any genetic manipulation of the embryo, creation of hybrids, or trans-species fertilization (except when fertilization of the egg of another species with human sperm is used for diagnosis of subfertility) is forbidden.

Surrogate Mothers

The recommendations of the Warnock Committee to forbid surrogacy agencies led to the passage of the Surrogacy Arrangements Act in 1985, which banned commercial surrogacy in the United Kingdom. The act has accomplished the purpose of suppressing surrogacy agencies; such arrangements will likely continue to occur, however, as surrogates and commissioning parents are exempt from criminal liability, and private surrogacy arrangements are not prohibited.

The White Paper decided against licensing noncommercial surrogacy services and emphasized that any contract drawn up as part of a surrogacy arrangement will be unenforceable in the United Kingdom courts.

OTHER NATIONAL EFFORTS REGARDING NONCOITAL REPRODUCTION

Argentina

Five centers for infertility treatment in Argentina offer artificial insemination, IVF, and gamete intrafallopian transfer. None of these procedures is currently regulated by law, but legislators are examining the relevant issues (76).

Infertility treatment is covered by health insurance and is offered throughout the country in specialized hospitals; however, artificial insemination must be paid for by the patient. Ethics committees function in some of these hospitals (76).

Austria

In 1986, two studies were published in Austria, one a national enquiry on family policy and the new reproductive technologies and the other a report of the Ministry of Science and Research on the fundamental aspects of genetics and reproductive biology (13). The Department of Justice is now preparing a bill that will regulate artificial procreation; of particular interest, it will allow posthumous insemination and surrogacy (23).

Artificial Insemination

Infertility treatment and artificial insemination are not currently regulated in Austria. Artificial insemination is not offered widely throughout the country, although some specialized hospitals and private physicians provide it. Infertility treatment in general is covered by health insurance but artificial insemination must be paid for by the patient (79).

The Ministry of Science and Research report recommended that donor sperm be used in artificial insemination and IVF only if the husband or partner is sterile and the woman and her husband or partner give informed consent to the procedure. If he has consented, the husband or partner cannot contest paternity, and the donor should have no legal rights to any resulting child.

The report recommended that the doctor be responsible for screening donors, keeping confidential records of the physical examination and the identity of the donor, and, if necessary, revealing medical facts to the recipients and the resulting children. These criteria should be applied to egg donation as well. Mixing sperm should be forbidden, and the use of frozen sperm by a widow should be allowed only within 10 months after her husband's death. Finally, no more than 10 conceptions should be allowed with any one donor's sperm.

In Vitro Fertilization

The Ministry of Science and Research report recommended that IVF only be used to ameliorate infertility after other treatments have failed, or when medical treatment is too risky or without hope. There must be reasonable hope for success, and precautions must be taken to ensure that there is no risk to the mother or child. The procedure should only be offered to couples who are married or in a stable relationship and who show that they would offer a satisfactory home for a child.

A couple can accept a donated egg or embryo if all other treatment possibilities have been exhausted, if the husband (or partner) agrees, if the egg has been fertilized in vivo or in vitro with the husband's sperm, and if the woman is younger than 45 years old. The report specified that doctors should not fertilize more eggs than they intend to transfer back to the woman; if more embryos are created, however, freezing them is allowed. Frozen embryos should be used by the couple from whom the gametes originated. If not, they can be donated. If no infertile couples need the embryos, then they may be used for research, provided the parents give permission. In no case should embryos be implanted after they have been frozen for 3 years.

Research on Preimplantation Embryos

The report states that research should be performed only on embryos that have no hope of implantation. Before the research commences, the researchers must show that medical progress can be made from this experimentation and must check with their local Institutional Review Board. Experimentation is expressly prohibited if the possibility for animal research is not exhausted; if the embryo is more than 14 days old; if the embryo is used for routine experiments; if researchers are attempting to create clones, chimeras, or human/animal hybrids; or if the point of the experiment is not to prevent or cure disease but to create humans with special characteristics.

Surrogate Mothers

Surrogate motherhood should not be allowed, according to the Ministry of Science and Research report.

Belgium

Currently artificial insemination by donor is dealt with mainly by the courts in Belgium. It can only be used for sterility or hereditary disease, payment of donors is not allowed, and the identity of the donor can only be revealed by court if necessary (24). The consent of the woman, her husband, and the donor is required. Absolute secrecy must be maintained. In 1987 a law was passed stating that a child born from artificial insemination by donor with the consent of the husband is legitimate and that the consenting husband cannot challenge paternity (23,35).

IVF is regularly practiced in the obstetrics departments of all medical schools and in a number of other centers (53). In 1987, the Government organized two colloquia dealing with reproductive techniques, one dealing mainly with judicial problems and the other with ethical and medical matters (23). Sharp differences between those who share the views of the Roman Catholic Church and others prevented these colloquia from reaching conclusions acceptable to a substantial majority, although a report (*Collogue National de Réflexion Scientifique*) was presented to the Belgian Secretary on the *State of Health and Bioethics in the 1990s* (21). This deadlock and the technological advances that constantly modify the practical problems encouraged governmental circles to postpone definite legislative proposals in this field (53).

Brazil

According to Brazil's 1957 Code of Medical Rules (Article 53), artificial insemination by donor is prohibited and artificial insemination by husband may be performed only with the consent of both spouses (24).

Bulgaria

Article 31 of Bulgaria's Family Code deals with artificial reproduction. It states that motherhood is determined through birth, regardless of the origin of the genetic material, and that the husband of a woman who undergoes artificial insemination by donor or accepts an oocyte donation cannot contest paternity if he consented to the procedure (24).

Chile

There is no specific legislation in Chile regarding noncoital reproduction. However, the Chilean Fertility Society and the Chilean Society of Obstetrics and Gynecology have developed guidelines concerning IVF. The two societies consider the procedure ethical if used for a married couple using their own gametes (37).

Colombia

Colombia's criminal code states that artificially inseminating a woman without her consent is a crime punishable by imprisonment (117).

Cyprus

There is no legal regulation of infertility treatment in Cyprus. The Government medical services provide limited facilities for infertility treatment but none for artificial insemination. Some private gynecologists offer artificial insemination at high costs (79).

Czechoslovakia

Czechoslovakian federal legislation (Family Law, Article 52-2, 1982) states that the consenting husband of a woman undergoing donor insemination may not contest paternity if the child was born between 6 and 10 months after artificial insemination was administered, unless it can be proved that the mother of the child became pregnant by means other than artificial insemination (24).

Two Czechoslovakian republics, the Czech Socialist republic and the Slovak Socialist republic, have passed legislation based on the 1982 federal legislation. They state that artificial insemination may be performed only when health reasons exist for such an intervention; that a medical examination must be performed on the parties involved; that written permission must be obtained for the procedure by both husband and wife; that donors must be healthy, without evident genetic defect; that the couple and donor may not learn each other's identities; and that all circumstances involved with artificial insemination must be kept confidential (24). The legislation does not explicitly state that the couple must be married, but in the legislation they are always referred to as husband and wife.

Denmark

Currently no regulations cover infertility treatment in Denmark, but artificial insemination by donor is performed only in public hospitals (79). In 1953 a Commission appointed by the Danish Ministry of Justice issued a report recommending a law on artificial insemination. No legislative action was taken in response. However, the report recommended that physicians performing donor insemination choose the donor and keep the identity of both the donor and the couple confidential, and these rules are generally followed in current practice (68). Oocyte donation and surrogate motherhood have not been accepted in Denmark (69).

A committee under the Danish Government published a report on *Ethical Problems with Egg Transplantation, AID and Research on Embryos* in 1984. The conclusion of this report was that legislation concerning these techniques was unnecessary but that a standing review and advisory ethics committee should supervise their use. This committee will begin to function in 1988 (69).

In 1987 a law was passed forbidding all research on human embryos until a National Ethics Committee proposes guidelines for such research to Parliament (23).

Egypt

Artificial insemination by husband is allowed in Egypt, while artificial insemination by donor is not. One center offering artificial insemination by husband and IVF reports that these technologies are accepted on a social level in Egypt but are still resisted by some doctors. A number of other centers are developing slowly.

The use of IVF on infertile couples is permissible under Islam if the couple is married, the gametes come from the couple, and the embryo is implanted into the wife. Cryopreservation of sperm, oocytes, and embryos is not clearly addressed by religious authorities. Surrogate motherhood is forbidden by religious regulations (63).

Finland

There are no regulations specifically covering infertility treatment in Finland, but treatment is available from hospitals and the Finnish family planning agencies free of charge (79).

German Democratic Republic

Artificial insemination by donor and IVF are considered ethically acceptable in East Germany. Artificial insemination by donor is offered through special centers, following the written agreement of the infertile couple that any resulting child will be regarded as legitimate (79). Oocyte and embryo donation are also accepted, with the informed consent of the genetic parents. The sale and purchase of human gametes or embryos is forbidden, as is surrogacy. The transfer of frozen embryos is discouraged until there is no risk involved in the procedure (137). However, there are no regulations governing infertility treatments.

Greece

There are five IVF centers and one frozen sperm bank in operation in Greece, and artificial insemination by donor has been practiced there for the last 23 years. Article 1 471/2-2 of Greek Civil Code, Law 1329, of February 1983, states that a husband who has consented to his wife undergoing artificial insemination by donor cannot disavow his paternity regarding the resulting child (24).

IVF, frozen and fresh sperm banks, surrogate mothering, and embryo freezing are all illegal in Greece. Thus, although these medical procedures are carried out, they are in essence being done illegally. The Greek Orthodox Church also opposes surrogate motherhood (78).

Hungary

Two pieces of legislation relate to infertility treatment in Hungary. Ordinance No. 12 of the Ministry of Health states that artificial insemination may be carried out on any woman under 40 who resides in Hungary; is in full possession of her physical and mental faculties; and is unlikely, according to medical opinion, to conceive naturally. Artificial insemination is normally carried out using the husband's semen. The use of donor sperm may only be considered if insemination using the husband's semen is unlikely, according to medical opinion, to result in the birth of a healthy child. A donor must not be suffering from any hereditary disease, and physicians must observe strict confidentiality regarding the identity of the donor (24).

The National Institute of Obstetrics and Gynecology and the National Institute of Urology issued a circular pursuant to Ordinance No. 12. The circular states that potential sperm donors must be healthy, intelligent, and free of hereditary disease. Furthermore, potential donors must undergo the following tests: a genetic examination, determination of blood group and Rh factor, a psychological examination, and a test to detect the presence of sexually transmitted diseases. The physician carrying out the insemination and the personnel of the establishment in which it is carried out are required to keep the identity of the donor and the procedure confidential (117).

Article 38-1 of the Law on Marriage, Family, and the Care of Children (1974) states that except when the husband or partner of a woman undergoing artificial insemination recognizes paternity of the resulting child, paternity can only be determined in court. However, the court cannot establish paternity when artificial insemination has been used. These provisions ensure that the sperm donor will have no rights or duties to the resulting child. The presumption of paternity can be contested if the husband can prove that he did not have sexual relations with the woman at the time of conception or if he did not consent to his spouse's artificial insemination (24).

Iceland

More than 50 children have been conceived by artificial insemination since 1979. Donor sperm comes from Denmark to avoid problems of consanguinity due to the small size of the population. Artificial insemination by donor is the only method of noncoital reproduction currently used in Iceland (24).

During the 1985/86 parliamentary session, Parliament passed a resolution asking the Ministry of Justice to form a study commission to look at the legal aspects of artificial insemination (24), as there currently is no legislation on any aspect of noncoital reproduction.

India

IVF is now officially encouraged as a treatment for infertility, despite India's overall objective of slowing population growth. The Indian Council for Medical Research first sanctioned IVF in 1983 and began a research program at the Institute for Research in Reproduction in Bombay. There is now considerable public interest in IVF. Many private clinics as well as Government-run facilities offer the procedure (62).

Ireland

Artificial insemination by donor and IVF are performed in Ireland. In 1985 the Medical Council of Ireland approved guidelines promulgated by the Institute of Obstetricians and Gynaecologists. Therapeutic application of IVF is authorized provided the couple is married, no donor gametes are used, and all embryos created are placed into the woman undergoing the procedure. Experimentation on and freezing of embryos is considered unacceptable (23).

Italy

In 1984, the Minister of Health appointed the Commissione Ministerale per una Specifica Normatica in Terma di Fecondazione Artificiale Umana to study reproductive technologies. The resulting document, the Santosuosso Report (published in 1985), proposed two bills—one dealing with artificial insemination and the other with artificial insemination by donor, surrogacy, and other issues—and included two introductory essays (80).

No legislation has been passed as yet in response to the Santosuosso Report. The report proposed that artificial insemination by husband and donor be permitted, but be limited to married couples, and that donor insemination be available only when adoption is not granted within 6 months of application (136). In 1987, the Italian Government issued a regulation requiring that all donors undergo tests for hepatitis and sexually transmitted diseases. Furthermore, the Ministry of Health is preparing a registry listing all public and private centers where artificial insemination is practiced and plans to create a data bank on the results of the procedures (136).

IVF has been the subject of considerable discussion during the past several years in Italy. Six bills have been proposed, but none has been debated in Parliament (80). In 1984, a group of gynecologists and researchers in Italy made the following recommendations for the practice of IVF:

- IVF is justified only when other therapeutic techniques have been unsuccessful or have no possibility of success, or when alternative therapeutic techniques are too risky;
- the couple must be married and be adequately informed about the technique and related risks;
- embryos should be reimplanted, whenever possible;
- donor eggs and sperm are acceptable in principle, but IVF embryos should not be donated from one couple to another;
- research on embryos for commercial purposes should not be allowed;
- manipulation on the genotype of germ cells should not be allowed;
- IVF must be carried out under the direction of a physician in a facility authorized by the Ministry of Public Health; and
- a national ethics committee should be established to formulate guidelines (24).

Japan

Japanese attitudes concerning noncoital reproductive technologies are divided. Currently no law deals with any of the technologies, but various professional organizations have issued relevant guidelines (14), such as the 1985 guidelines issued by the Japanese Obstetrics and Gynecology Society (21).

Only one hospital offers artificial insemination by donor in Japan at the moment, and no sperm bank facilities exist. Sperm donors are paid, and they are usually medical students or others with some affiliation to the hospital. Estimates indicate that approximately 10,000 children have been born in Japan as a result of donor insemination (14). The medical profession in Japan preserves the anonymity of sperm donors; records are kept but no information is made available to recipients of sperm (14).

No law establishes the status of these children. However, many legal scholars have construed existing law to presume that the child of a married woman conceived by donor insemination is the legitimate child of her husband, provided the procedure is carried out according to current practice (14).

The first IVF baby in Japan was born in 1983, and currently about 30 institutions perform the procedure. The guidelines of the Japanese Obstetrics and Gynecological Society state that IVF must be limited to married couples. Oocyte donation and surrogate motherhood are not practiced in Japan (14).

The Japanese Obstetrics and Gynecology Society has also recommended that a fertilized egg can be used for experimentation up to 14 days, with the consent of the donors (14).

Libya

Artificial insemination by donor is criminal in Libya. Libya's criminal code (articles 304A and B) states that anyone who artificially inseminates a woman by force, threat, or deceit is to be punished by imprisonment. Furthermore, a woman who consents to artificial insemination or who attempts to artificially inseminate herself is to be punished with imprisonment. The husband is also punished if the insemination took place with his consent. It is not clear if these prohibitions extend to artificial insemination with the husband's sperm (24).

Luxembourg

An official committee under the Director of the National Laboratory of Health has been charged with proposing guidelines for the use of medically assisted procreation. Its report was submitted to the Government in 1986 (24).

Mexico

There is no legislation regarding reproductive technology in Mexico, nor are there published reports studying the relevant issues. Infertility programs are available, however, for couples desiring to have children. Due to the expense involved with such programs, they are offered primarily by Government institutions. The procedures available are IVF and gamete intrafallopian transfer, using only gametes of the couple. Mexicans have not used donated gametes or surrogate mothers to date. Cryopreservation of embryos is currently available at one program (111).

Although there are no national regulations related to reproductive technologies, the Government institutes have adopted the declarations of the American Fertility Society and the Queen Victoria Medical Center from Melbourne, Australia, as a basis for self-regulation. To accept a couple for treatment, the institutions require that the woman be 20 to 35 years old; that ovulation occur; that the infertility be caused by a tubal factor, perineal factor, immunologic factor, or another kind of undetermined infertility; and that the couple have no more than one child already (111).

The Netherlands

All noncoital reproductive technologies are available in Holland, and research on the embryo is being discussed. In 1986, the independent Health Council of the Netherlands submitted a report on reproductive technologies to the Minister and State Secretary of Health (43). The report discusses the technical, psychosocial, and ethical aspects of noncoital reproduction, in particular artificial insemination by donor, IVF, egg donation, and surrogacy.

Artificial Insemination

The use of artificial insemination by donor is fairly common in the Netherlands, resulting in the birth of approximately 1,000 children per year (43). Holland's Civil Code denies the husband of a woman undergoing donor insemination the right to contest the paternity of any resulting child if he has consented to the procedure (24). General agreement exists that sperm donors have no responsibility for children resulting from their sperm (70). A working group of the Association of Family and Youth recently recommended that legislation ensure this situation (43).

The Health Council of the Netherlands considered the use of donor insemination or IVF by a woman without a male partner acceptable in certain circumstances. It recommended that prospective sperm donors be screened for heightened genetic risks and infectious diseases. A sperm bank should only be allowed to reject a donor on these grounds. Only frozen sperm should be used, and sperm from different donors should not be mixed. The Council recommended that children conceived by donor insemination be informed about their manner of conception and relevant genetic information but not about the identity of the donor. The number of inseminations allowed per donor should be limited. Finally, donors should not be paid for their sperm, only their travel expenses (99).

Oocyte Donation

The Health Council also considered noncommercial egg donation acceptable. They recommended that more detailed legislation is needed regarding the right of ownership of human egg and sperm cells. Recipients of donor eggs should also sign informed consent statements. Regarding donated gametes generally, the Council felt that parents should be encouraged to inform their children of the nature of their origin but should have the freedom to decide how and when to inform the child (99)

In Vitro Fertilization

IVF is available in the Netherlands. In 1985, however, the Minister of Health decided that for the time being IVF would not be covered routinely by the sickness funds, a public health insurance system that covers people whose yearly income is below fl. 50,000 (about $20,000) (43).

The Health Council report concluded that the results of IVF in relation to the costs have roughly come to match those of tubal surgery, so IVF should no longer be limited on medical grounds. IVF centers should be subject to certain requirements that would ensure high quality care and adequate ethical review. As with artificial insemination by donor, the couple undergoing treatment must give written informed consent, indicating at the same time what should be done with any excess embryos. Cryopreservation of embryos was also found acceptable, within certain time limits (99).

Research on Preimplantation Embryos

The Health Council stated that preimplantation embryos should be approved for research provided "that major interests of a large number of people are at stake; that the data could not be obtained by different means; that both partners have given their consent; and that the research proposal has been vetted and approved not just by the medical ethics committee of the hospital in question but also by a national committee" (99). Furthermore, they recommended that the legal status of the preimplantation embryo, the authority over the embryo by its genetic parents, and the functioning of embryo banks should be regulated by law. Selling embryos should be prohibited (99). No general agreement exists in the Netherlands concerning this research (70).

Surrogate Mothers

The Health Council considered noncommercial surrogacy arrangements acceptable for medical reasons only and stated that commercial surrogacy should be forbidden by law. Their report recommended that a Government-supervised body (resembling an adoption agency) should be responsible for supervising surrogate arrangements.

The Council proposed that in principle a surrogate mother should part with the child right after birth. However, the surrogate mother should be allowed to claim a 3-month period to reconsider the transaction. The "claim" should be made (and granted) prior to the child being given up. Once the child has been handed over to the adoptive parents, a claim should be considered invalid (99).

New Zealand

In 1985, the Law Reform Division of New Zealand's Department of Justice published a comprehensive issues paper specifically to encourage "informed public debate" on new developments in reproductive technology (87). Twenty-one months later the Division published an extensive summary of the submissions it had received (88).

New Zealanders hold a variety of opinions concerning these technologies, with no one view favored by a clear majority (41,88). There are religious objections to every procedure, feminist objections, strong advocacy views from infertility associations, and various intermediate positions.

In 1986 the Government introduced to Parliament a bill to amend the Status of Children Act 1969. The purpose of the bill was to clarify the legal status of children conceived through the use of donated sperm, donated ova, or donated embryos using the techniques of artificial insemination by donor, IVF, or gamete intrafallopian transfer. Not all these techniques are currently available in New Zealand. The bill, known as the Status of Children Amendment Act 1987, provides that the consenting husband of a woman receiving donor insemination is the legal father of the child. The husband's consent is presumed unless evidence indicates otherwise. When oocyte donation occurs, the birth mother is the child's legal mother. Sperm and ova donors lose all rights and responsibilities of parenthood. If the husband does not consent to the procedure or if the mother is single, the donor is the legal father, but he holds no rights or responsibilities regarding the child unless he marries the mother. The bill does not discuss a child's access to information about his or her genetic parentage because there is no statutory prohibition on the release of such information.

In 1986, the Minister of Justice set up a three-member committee to "monitor the issues associated with alternative methods of reproduction and to advise the government as required," with one member each from the Ministry of Women's Affairs, the Department of Health, and the Department of Justice (100).

Artificial Insemination

During the past 10 years, artificial insemination by donor has been performed at major centers in Auckland, Wellington, Christchurch, and Dunedin; in smaller centers in Hamilton, Napier, and New Plymouth; and by some individual physicians. Some of these clinics do not operate continuously; some close temporarily, usually for lack of donors. One 1987 estimate stated that one child a week is born as a result of artificial insemination by donor (100). Currently all the centers freeze semen for 3 months to test donors for acquired immunodeficiency syndrome. Policies vary from center to center regarding the age of wife, husband, and donor; the screening, recruitment, and reimbursement of donors; and recordkeeping (87).

In Vitro Fertilization

There is one state-funded IVF program in New Zealand, located in Auckland, which produced its first baby in 1984. As of November 1986, 28 IVF babies had been born (100). The IVF program uses no donor gametes. A private clinic was set up in Auckland in 1987 that offers gamete intrafallopian transfer and transvaginal ultrasonically directed oocyte retrieval. Because of the limited facilities and long waiting lists, many infertile New Zealanders go to Australia for IVF (59).

Norway

Two groups in Norway have addressed issues raised by novel reproductive techniques. In 1983, the Council of Medical Research issued ethical directives for artificial insemination and IVF (40). In 1986 a group of ministers proposed a law on both procedures (24), which the Norwegian Parliament adopted in 1987 (Act No. 68 of June 12, 1987).

The 1983 directives stated that artificial insemination and IVF should be limited to married couples or unmarried couples in a stable relationship. There should be uniform law concerning the anonymity of donors, and any children conceived with donated gametes should be considered legitimate. Sperm banks should be regulated by public law. A registration for donors should be instituted for eggs and sperm not immediately used in artificial insemination and IVF. The recipient of donated gametes and any resulting child should have access to medical information about the donor. Finally, research on sperm, eggs, and embryos should be reviewed by medical ethics committees.

The 1987 law states that artificial insemination and IVF are available only to married couples or couples in a stable relationship, that written consent must be obtained, and that the doctor must perform a medical and psychosocial evaluation. Artificial insemination by donor may only take place if the husband is infertile or the carrier of a grave hereditary disease, and IVF may only take place if the woman is otherwise sterile. The doctor must choose the donor, who remains anonymous. The donor may not be given identifying information about the couple or the resulting child. For IVF, the couple's own gametes must be used, and the intended rearing mother must carry the child; gestational surrogacy is not allowed. An Amendment to the Children Act, passed on the same day, states that the consenting husband of a woman using donor sperm should be considered the legitimate father of the child, and that the donor has no legitimate claim to the child.

The 1987 law states that artificial insemination and IVF must take place only in designated hospitals under special authorization by the Ministry of Social Affairs and under the direction of specialists. Cryopreservation of sperm and embryos is allowed, but only at the designated hospitals. Embryos may not be stored for more than 12 months. By virtue of limits on the use of artificial insemination by donor and IVF, surrogacy is illegal in Norway.

Philippines

Although a small number of physicians perform artificial insemination or gamete intrafallopian transfer, the use of reproductive technology is not common in the Philippines. More governmental emphasis is placed on controlling the birth rate than on alleviating infertility (3).

Poland

There are no statutes concerning artificial insemination or IVF in Poland. However, a Supreme Court decision in 1984 stated that the consenting husband of a woman using donor sperm cannot contest paternity of the resulting child (24). Concerning IVF, several clinics have attempted the procedure with no apparent success so far. The state has no objections to the procedure, although the Church disapproves of it(123).

Portugal

A 1984 Portugese law on sex education and family planning mentions infertility explicitly, stating that the state must encourage its treatment by facilitating the creation of artificial insemination centers and specialized centers for prenatal diagnostics (24).

Since 1985, frozen sperm has been available through the University of Porto, and in 1986 Portugal's first sperm bank was created. Also in 1986, sperm banks became subject to licensing regulation; the regulations state that the donor should not be paid, should remain anonymous, should be within a certain age range, and should have had children previously. Furthermore, the collection, manipulation, and conservation of sperm must be done only by publicly created centers or private doctors specially licensed by the Ministry of Health (24).

According to Portugal's penal code (article 214), artificially inseminating a woman without her consent is punishable by imprisonment (24). Under the Civil Code (article 1839), as amended in 1977, a husband who has consented to donor insemination cannot deny paternity (117). The Department of Justice has set up a "committee for the regulation of new reproductive technologies" that will soon submit a bill concerning these technologies to the Parliament (23).

Spain

The first human sperm bank in Spain was set up in Barcelona in 1978 (77). Efforts to address the legal and ethical issues raised by artificial insemination and IVF increased with the 1986 reports of the Ministry of Justice (116) and the parliamentary commission for the Study of Human In Vitro Fertilization and Artificial Insemination (115). The commission presented 155 recommendations for legislative and regulatory action, covering diverse topics such as quality assurance for medical clinics and personnel offering noncoital reproductive techniques, national and regional recordkeeping of use of donor gametes, criteria for embryo donation and experimentation, screening for gamete donors and recipients, and regularization of the legal rights of gamete donors, rearing parents, and children conceived by noncoital means.

The special commission generally recommended that artificial insemination and IVF be available to married or stable unmarried heterosexual couples, but specifically suggested that homosexual couples be banned from their use. Use of a deceased partner's sperm, eggs, or embryo was specifically endorsed, although the resulting children should not inherit from the deceased genetic parent. Donor gametes should be made available to overcome sterility, and their collection and screening should be managed on a strictly noncommercial basis by licensed gamete banks. The commission also recommended that legislation be passed to ensure confidentiality of any individual's infertility, donation of gametes, use of donor gametes, or conception by noncoital means. Finally, limited forms of embryo experimentation were approved.

The special commission recommended the formation of a national commission (Comisión Nacional de Fecundación Asistida, or CNFA) with separate committees on artificial insemination, IVF, and public policy to issue interim regulations governing relevant medical practice and embryo research, pending legislative action. The CNFA could also review medical findings and approve use of new techniques, such as oocyte freezing or genetic therapy on embryos, as they become nonexperimental. The special commission suggested that regional commissions should be set up as well (115).

The Socialist wing in Parliament has proposed two pieces of legislation that address these issues. The first preserves donor anonymity and limits the number of donations per donor to six, and the second forbids the conception or abortion of embryos exclusively for donation and forbids commercial traffic in human embryo tissue (101).

Artificial Insemination

The special commission recommended that artificial insemination be performed at authorized health clinics, some of which would also operate as sperm and embryo banks, and as ova banks when that technology improves sufficiently. Donation should only be accepted from those in good medical and genetic health, as demonstrated by a physical examination and a karyotype, and could only be made with permission from the donor's spouse or partner after warning that children conceived by donor insemination might yet seek to challenge the constitutionality of limitations on their right to know their genetic parents. Donors would have to be warned that they may not seek parental rights to the children conceived with their gametes, and will not be told the identity or even number of children born to them, although they will be asked to discontinue participation after six children have been born (115).

Recipients would also be screened for general health, fertility, and freedom from infectious diseases. Single women could receive donor gametes for artificial insemination or IVF (although not at public expense) provided they could demonstrate the ability to provide an adequate home. Selection of a donor would be made by the bank, and not by the recipient. Every effort should be made to match the physical appearance of the recipient's partner, and he would be able to renounce paternity only if he could show that he never consented or that his consent was seriously uninformed. Recipients and offspring would have the right to obtain nonidentifying information about the donor (115).

In Vitro Fertilization

The special commission recommended that IVF be available only to overcome infertility or to avoid a grave hereditary disorder, but went on to say that should other uses be made legal, they ought not to be paid for by public funds. The commission especially noted that, as with artificial insemination, the technique should not be used for sex selection. The recommendations state that only seemingly healthy embryos should be implanted, and that no more than the optimal number for a safe, live birth should be implanted. Extra embryos could be frozen for their own future use, be donated by the genetic parents to transfer banks for distribution to other couples, or be given to laboratories for experimentation. The commission suggested a storage limit of 5 years for frozen embryos, subject to new technical developments. Genetic parents could express in writing their wishes regarding disposal of an embryo in the event of death, disease, or divorce (115).

Research on Preimplantation Embryos

With regard to embryo research, the special commission suggested that embryos might be donated by couples not wishing to use them for IVF, but that embryos ought not to be created solely for the purpose of doing research. A time limit of 14 days (not counting time frozen) was recommended. Research would have to be approved by the CNFA and found to have "positive" goals for individuals or society, such as broadening knowledge on the process of fertilization, causes of infertility and cancer, and techniques for contraception. Research on a particular embryo would only be allowed with permission of the genetic parents, and after they had been informed of the goals of the particular experiment. The commission noted that no research ought to be allowed that involves mixing human and other animal genes, that is performed on embryos or fetuses in utero, or that takes place on an embryo destined to be implanted. Genetic therapy for embryos would be permitted if it could be shown that the embryo exhibited traits for an identifiable and serious disorder, that no other medical or surgical therapy would be effective, and that genetic therapy has a reasonable chance of success (115).

Surrogate Mothers

Surrogate motherhood, whether paid or unpaid, was found unacceptable by the commission. It recommended that any health center offering surrogate matching should lose its authorization to offer IVF and artificial insemination, and that all parties to a surrogacy contract, including the lawyers, agencies, and physicians, should be subject to criminal penalties (115).

Switzerland

There is no legislation in Switzerland pertaining to infertility except that regarding paternity in cases of donor insemination. However, the individual cantons (the Swiss equivalent of states) are now making their own laws, based on the 1985 Swiss Academy of Medical Sciences' directives concerning IVF and 1981 directives on artificial insemination. In Switzerland, most areas of public health are under the authority of the cantons.

One referendum on public demand suggested that the Swiss Government amend the federal constitution to allow regulation of reproductive manipulation and research in human genetics. In response, a federal commission was formed in 1986 to study problems associated with noncoital reproduction and human genetic research. The commission's report is expected in mid-1988 (25,98). The Government will formulate an opinion based on the report. At this point, a procedure of consultation will be carried out, involving all interested parties. The result of the consultation, the referendum, and the Government opinion will be submitted to Parliament for debate and to formulate recommendations (139).

Artificial Insemination

Six centers in Switzerland currently provide artificial insemination by donor in public gynecological clinics (in Bern, Lausanne, Liestal, Locarno, St. Gallen, and Schaffhausen) (25). There are also private gynecologists in Zurich, Bern, and Geneva who provide insemination services. All six insemination centers and the private gynecologists performing the service belong to the Swiss Work Group for Artificial Insemination founded in 1977 to coordinate the activities of the centers, standardize working methods, and carry out scientific programs on a joint basis (25,28). The Swiss Work Group for Artificial Insemination has been subsumed in the Swiss Society of Fertility and Sterility, but the original directives are still in operation.

Donors at the six donor insemination centers are selected by physicians, and all centers apply the following criteria for acceptance of donors: social motivation for donating semen, normal psycho-intellectual state, normal genetic screen, normal clinical and laboratory tests, adequate sperm counts, and age between 20 and 40. One controversial point centers on the use of karyotyping (28). The work group is not concerned with inbreeding, as a given donor usually does not give semen for more than a year and as a significant proportion of the couples requesting artificial insemination by donor come from other countries; thus the number of children fathered by one donor is not regulated. The identity of the donor is never mentioned on the insemination record (26,28), but the 1985 referendum suggested that keeping the genetic parentage of a child hidden from that child should be forbidden, unless the law states that such information should not be available (24). With regard to the child's status, article 256-3 of the Swiss Civil Code (June 1975) states that a husband who has consented to artificial insemination by donor cannot contest the paternity of any resulting child (24).

In Vitro Fertilization

As of January 1988, there were four public centers (in Basel, Lausanne, Locarno, and Zurich) and two private clinics (in Geneva and Lausanne) providing IVF services in Switzerland (25,27).

Within the framework of the law on public health, the Canton of Geneva issued regulations based on the directives of the academy of Medical Sciences on IVF. The academy stated that IVF and embryo transfer must be conducted by a physician, and that the IVF team must follow the academy's guidelines. Both IVF and embryo transfer for a couple with sperm and ova from that couple are allowed. IVF using donor gametes is not allowed, according to the academy directives. In addition, the transfer of embryos from one woman to another is banned by the academy (31), and the the referendum also suggested that the creation of embryo reserves for donation to other couples should be forbidden.

Research on Preimplantation Embryos

The academy directives state that embryos may be kept alive only during the course of treatment, and that research on human embryos must not be allowed (31). The 1985 referendum proposed that research toward extrauterine pregnancy, cloning, and chimeras should be forbidden, and that the manipulation of embryos or human fetuses such that their development is interrupted should not be allowed. Finally, the referendum disapproved of the commercialization of embryos (24).

Surrogate Mothers

The academy directives and the referendum both agree that IVF and embryo transfer must not be used to initiate surrogate motherhood (24,31).

Turkey

No legal regulation in Turkey covers infertility treatment, but it is generally provided in hospitals as part of standard medical treatment (79).

Yugoslavia

Two of Yugoslavia's republics, Croatia and Slovenia, have enacted laws concerning the right to medically assisted conception. These laws state that women and men have the right to diagnosis of the fertility problem and the right to attempt a remedy. Low fertility, according to the legislation, will be remedied by treatment—such as professional counseling, medication, or surgical procedure—and by artificial insemination (24).

Artificial insemination by husband is not only legal in Yugoslavia but is also a right of any infertile couple. Artificial insemination by donor is permitted in all the republics and provinces of Yugoslavia. In Croatia and Slovenia, where current law outlines the practice of artificial insemination by donor in more detail, the procedure must be performed by specified medical organizations, and it may only be performed when the spouses cannot fulfill their desire for children any other way. Legislation in Croatia and Slovenia states that artificial insemination may be performed upon any healthy adult woman of childbearing age (117).

Legislation in Croatia and Slovenia also states that the semen donor must be healthy. The donor is not entitled to any compensation for his semen. Slovenian law further specifies that a woman may not be artificially inseminated with the semen of a man who could not legally marry her for reasons of consanguinity. Legislation in both Croatia and Slovenia requires that the identities of the semen donor, the inseminated woman, and her husband be kept confidential (24).

In Croatia, legislation explicitly requires the consent of the recipient's husband. Other republics, lacking an explicit consent requirement, nonetheless state that lack of consent means that a husband can contest paternity of a child conceived by donor insemination. These republics include Slovenia, Bosna, Hercegovina, Kosovo, Macedonia, Montenegro, Serbia, and Vojvodina (117).

INTERNATIONAL ORGANIZATIONS

Council of Europe

In 1987 the Council of Europe's Ad Hoc Committee of Experts on Progress in the Biomedical Sciences (CAHBI) submitted proposed principles (38) on the use of noncoital reproductive techniques to the Council of Europe's Committee of Ministers (20). These principles were the subject of a 1986 hearing in Trieste, Italy, that included nongovernmental international organizations. The principles are now being finalized. The Parliamentary Assembly of the Council of Europe also contributed recommendations to the Committee of Ministers (39) concerning the use of human embryos and fetuses for diagnostic, therapeutic, scientific, industrial, and commercial purposes. The Ad Hoc Committee's principles do not currently represent the official position of either the Council of Europe or the member states; the Committee of Ministers of the Council of Europe will decide whether the proposed guidelines should be adopted (23).

CAHBI concerned itself with "artificial procreation," defined to include artificial insemination; in vitro fertilization; methods involving donation of semen, ova, and embryos; and certain procedures carried out on embryos. CAHBI concluded that the availability of artificial procreation techniques should be limited to heterosexual couples with a medical need (defined as infertility or disease that would result in the child's early death or having a severe handicap, such as Huntington's chorea). Selecting sex or special characteristics through artificial procreation is explicitly prohibited.

Noncoital reproduction may only be used if the persons involved have freely given informed consent expressed in writing. Furthermore, it is the physician's responsibility to ensure that the participants receive appropriate information and counseling about possible medical, legal, and social implications of the treatment. Only licensed physicians can perform these techniques, and both physicians and clinics must screen donors for hereditary and infectious disease.

CAHBI stated that the number of children born from the gametes of any one donor should be limited and that the donor (as well as any organization authorized to offer gametes for artificial procreation or research) should not receive any profit. Gametes stored for the future use of the donor must be destroyed if the donor dies or cannot be located when the storage term expires.

If donor gametes are used, the provisions state that the woman who gives birth to the child shall be considered the legal mother and her husband or partner will be considered the legal father, provided he has given his consent. The donor will have no rights or responsibilities to the child. CAHBI did not reach any conclusions concerning the anonymity of donors and the right of the child to gain access to information about the donor, choosing to leave this decision to the member countries.

In principle, CAHBI felt that IVF should be performed only with the original couple's gametes; in exceptional cases, however, donated gametes and even donated embryos (only surplus embryos from another couple's IVF procedure) may be used.

CAHBI provisions state that the creation of embryos for research purposes is forbidden, and that research on embryos is only allowed if it benefits the embryo or is an observational study that does the embryo no harm. If the member countries do allow other research, however, the following strict conditions should be observed: the research must have preventive, diagnostic, or therapeutic purposes for grave diseases of the embryo; other methods of achieving the purpose of the research must have been exhausted; no embryo should be used later than 14 days after fertilization; the consent of the donating couple must be obtained; and a multidisciplinary ethics committee must approve the proposed research.

The Parliamentary Assembly submitted a formal recommendation to the Committee of Ministers, in general stating that no diagnostic or therapeutic intervention should be allowed on an embryo in vivo or in vitro except for the well-being of the child; that embryos should not be created for purposes of research; and that certain techniques, such as cloning or producing chimeras, should be forbidden altogether (39).

The CAHBI provisions state that contracts for surrogate motherhood should be unenforceable, and intermediaries and advertising should be forbidden. Surrogate motherhood should be allowed only if the surrogate does not receive material compensation.

European Parliament

The European Parliament has various committees looking at the problems surrounding noncoital reproduction, including its Committee on Legal Affairs and Citizens' Rights. No formal statement has been issued to date.

Since 1984, however, five bills have been proposed in the Parliament concerning reproductive technologies. These include:

- A resolution proposed in February 1985 by Marshal condemning "mechanical adultery" and surrogate motherhood. The resolution encouraged member states to facilitate adoption, discourage abortion, and pass legislation making surrogate motherhood criminal.

- A resolution proposed in October 1984 by the Christian Democratic Party suggesting that the member states introduce legislation regulating experiments concerning human genetics and work toward harmonizing the laws of the various member states. They recommended setting up a commission to study the relevant issues.
- A resolution proposed in October 1984 by the Socialist Party asking for a commission to study the problems surrounding all the reproductive technologies, including eugenics and sex selection.
- A resolution proposed in September 1984 by Lizin asking for a general code on artificial insemination for the European Community.
- A resolution proposed in August 1984 by Habsburg and others urging that embryos be given the rights of children, that the scientific use of embryos be forbidden, and that all forms of experimentation on human embryos be ended (24).

None of these bills were ever approved by the European Parliament.

Feminist International Network of Resistance to Reproductive and Genetic Engineering

FINRRAGE is an organization of feminists concerned with the effects of reproductive technology and genetic engineering on the social position and biological integrity of women. The organization has held several conferences dealing with these issues, including one in Brussels in 1986. (A general discussion of feminist views on reproductive technologies can be found in app. D.)

The main conclusion of the Women's Hearing on Genetic Engineering and Reproductive Technologies at the European Parliament in Brussels (attended by more than 140 women from 10 member states of the European Community) was a consensus that "the approach by official committees, doctors' associations, churches, etc. (and the Legal Affairs Committee of the European Parliament) was less than satisfactory" (56). The women felt that the prevailing view centers on the fetus and ignores women's interests. A summary of the proceedings ended with the following "conclusions and demands," quoted verbatim from the text:

> FINRRAGE demands:
>
> - research into the (complex) causes of sterility and reduced fertility (for example post-appendicitis infections, hormone treatments, intra-uterine pessaries, environmental influences etc.) and promotion and development of alternative methods of treatment.
> - comprehensive information on the risks, possible long-term effects and minimal prospects of success of IVF treatment.
> - creation of an autonomous women's research and information center on reproductive and genetic engineering.
> - political and financial support for autonomous women's groups working the fields of reproductive and genetic engineering, pharmacology and health.
> - resumption of the discussion in official committees and ethical committees taking account of the above views and with effective participation by women's initiatives which for a long time have been carrying out excellent research and information work in this field.
> - rejection of any compulsory counseling and examination.
> - repudiation of legislative measures which would block access by certain groups of the population (for example single or lesbian women) to methods such as artificial insemination by donors.
> - an immediate ban on the use of medicaments which can be proved to have harmful effects or involve risks.
> - no delay until the possible later harmful effects of IVF treatment are revealed for women and children but a reversal of the burden of proof particularly as regards long-term effects (the decision by the cabinet of the Land Government in the Saarland providing for an interim ban on IVF treatment is significant in this context).
> - recognition that only women have a legislative right to decide on whether to make use of antenatal examinations (amniocentesis, chorionic villus sampling, etc.) or not or whether to terminate a pregnancy or not (56).

World Health Organization

The World Health Organization held a meeting in Copenhagen in 1985 to discuss infertility and the various reproductive technologies that have been developed. Participants of the meeting made seven recommendations, which are summarized here.

- A report should be prepared on the medical, psychosocial, demographic, economic, ethical, and legal aspects of the latest developments in noncoital reproductive techniques.
- A study should be prepared and implemented in selected member states on public knowledge, needs, and attitudes concerning infertility and reproductive technologies.
- The above two reports should be disseminated to relevant Government agencies, professional organizations, the media, consumer groups, and the general public.
- Guidelines for clinical and research applications of noncoital reproductive techniques need to be developed.

- The activities of ethics committees in member states need to be tracked and Governments should be encouraged to establish such committees.
- The teaching of ethics as part of health professional training should be encouraged.
- It is necessary to promote the establishment of national registers to monitor the use and outcome of noncoital reproductive techniques (138).

World Medical Association

In Brussels in 1985, the 372d Congress of the World Medical Association adopted a resolution calling for all physicians to abide by a uniform set of principles of ethical practice with regard to IVF. It urged physicians to briefly explain to their patients the purpose, risks, inconveniences, and failures of IVF therapy. When donor sperm, eggs, or embryos are used, physicians should clearly explain the risks associated with these procedures as well, particularly risks associated with freezing embryos. When the donors are not the intended rearing parents, the physician should explain to the donors the consequence of their intentions to relinquish all claims to the resulting child, and to the recipients that they will be responsible for the child regardless of its health. It also called on physicians to refrain from reimplanting any embryos used for experimentation, and stated that the Helsinki Declaration on the protection of human research subjects should apply to embryo research as well. With regard to commercialized surrogate motherhood, the World Medical Association found the practice unethical (35).

SUMMARY AND CONCLUSIONS

In general, artificial insemination by husband and donor are considered acceptable techniques worldwide. Several countries have adopted legislation stating a child conceived from donor insemination is the legitimate child of his or her mother and her consenting husband. IVF is also generally considered acceptable, provided it is used only when medically necessary.

The use of artificial insemination and IVF for unmarried couples, homosexual couples, and single men and women is more controversial. The use of donor gametes in IVF is not universally accepted either. Oocyte donation is not as widely accepted as sperm donation, largely because the technology involved is considered experimental. Acceptance of embryo donation also varies widely.

Most controversial, however, are the topics of research on human embryos and surrogate motherhood. Countries that do approve embryo research often stipulate that the embryos used must have been left over from therapeutic IVF attempts, not deliberately created for research, and they often impose a time limit after which research must end. Surrogate motherhood has achieved little acceptance, and several countries have taken positive steps to ban the practice, especially its commercial use.

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Appendix F

Religious Perspectives

It is estimated that about 60 percent of Americans, or 140 million people, belong to some established religious community. Table F-1 provides a membership estimate for the major religious groups in the United States. Table F-2 provides an overview of judgments about the licitness of reproductive technologies from the standpoint of each tradition.

This appendix both surveys these viewpoints and attempts to predict their present and future impacts on individual choices and on community policy formulation (3).

At least three factors help determine the influence of religious viewpoints: the size of the relevant community, the authority of the current viewpoints within the community, and the unanimity and diversity of opinion in the relevant community.

The larger the community, all other things being equal, the more infertile couples there will be whose individual treatment decisions are influenced by the community's viewpoints and the more adherents there will be who address public policy formulation in light of those views. By the same token, the weight and authority of specific religious viewpoints will influence the number of adherents who draw on these views in considering public policy issues.

At one extreme are communities that emphasize the importance of individual judgments. These include religious communities such as the Baptists and the Evangelicals. At the other extreme are traditions with centralized teaching authorities, such as the Roman Catholic Church. In between are communities that formulate general policies at organized centralized meetings but that see these policies as reflections of current thinking rather than as authoritative teachings. These include the decisions of the General Conven-

Table F-1.—Membership Estimates, Selected Religious Groups in the United States

Denomination	Membership
Roman Catholic Church	52,393,000
Southern Baptist Convention	14,178,000
United Methodist Church	9,405,000
Lutheran Churches	7,877,000
Jewish	5,027,000
Mormon Churches	3,602,000
Presbyterian Churches (Reformed)	3,122,000
Episcopal Church	2,795,000
Muslims	2,000,000
Greek Orthodox Church	1,950,000
United Church of Christ	1,702,000
Jehovah's Witnesses	650,000
Seventh Day Adventists	624,000
Mennonite Churches	110,000

SOURCE: U.S. Department of Commerce, *Statistical Abstract of the United States*, 106th ed. (Washington, DC: 1985).

Table F-2.—Summary Table of Religious Perspectives

	Traditional infertility workups	AIH	IVF with spousal gamete and no embryo wastage	AID	IVF with no restrictions	Surrogate motherhood
Roman Catholic	No	No	No	No	No	No
Eastern Orthodox	Yes	Yes	No	No	No	No
Anglican	Yes	Yes	Yes	*	*	No
Lutheran	Yes	Yes	Yes	No	No	No
Reformed	Yes	Yes	Yes	*	*	No
Methodist	Yes	Yes	Yes	No	No	No
Mennonite	Yes	Yes	Yes	*	*	*
Baptist	Yes	Yes	Yes	*	*	*
Evangelical	Yes	Yes	Yes	No	No	No
Adventist	Yes	Yes	Yes	*	*	No
Christian Scientist	No	Yes	No	Yes	No	Yes
Jehovah's Witness	Yes	Yes	Yes	No	No	No
Mormon	Yes	Yes	Yes	*	No	No
Orthodox Jewish	Yes	Yes	Yes	No	No	No
Conservative Jewish	Yes	Yes	Yes	Yes	Yes	*
Reform Jewish	Yes	Yes	Yes	Yes	Yes	Yes
Muslim	Yes	Yes	Yes	No	No	No

Abbreviations: AIH—artificial insemination by husband, IVF—in vitro fertilization, AID—artificial insemination by donor.
Yes = Accepted as licit.
No = Illicit.
* = Controversial or dependent licitness.

SOURCE: Office of Technology Assessment, 1988.

tion of the Episcopalian Church, the General Assembly of the Presbyterian Church, and the General Conference of the United Methodist Church. Also in between are communities that emphasize the authority of leading religious scholars, while recognizing that these scholars may disagree. These include the Muslim community and the Jewish community.

The final factor to consider is the unanimity and diversity of opinion in the relevant community. The greater the diversity of opinion, the less constrained individual infertile couples will feel when confronting choices about particular treatment decisions, and the less the community in question will be able to influence public policy decisions (3).

Roman Catholic

Interventions designed to augment the possibility of procreation through normal conjugal relations are morally licit (e.g., gamete intrafallopian transfer). Infertility workups that involve masturbation are morally dubious. All forms of artificial insemination, in vitro fertilization (IVF), and surrogate motherhood are rejected as morally illicit. The desire to procreate does not justify what is morally illicit (7,21-23).

Eastern Orthodox

Infertility workups and medical and surgical treatments of infertility for married couples are advisable because of the significance of procreation. Artificial insemination by husband is morally acceptable and may even be advisable if needed, although artificial insemination by donor is rejected as a form of adultery. IVF is absolutely rejected when it involves the destruction of zygotes and is not recommended even if only one egg is fertilized. Surrogate motherhood is rejected. This teaching applies to the case when both gametes come from the married couple (who would also be the social parents) (9,16).

Interdenominational Protestant

The significance of procreation in the life of the community and in the life of individuals who want children leads to the appropriateness of society supporting the treatment of infertility for married couples so long as the treatment does not lead to a dehumanization of procreation or to a violation of covenantal relations. The most acceptable treatments of infertility are the traditional medical and surgical interventions and artificial insemination by husband. IVF using gametes from a married couple and avoiding harm to any zygotes is probably also acceptable. Artificial insemination by donor, IVF that does not meet the stipulated requirements, and all forms of surrogate motherhood are at best morally questionable and at worst morally illicit (12,24,34,40).

These stipulations do not apply to a number of major Protestant denominations. The Pentecostalist churches, particularly the Assemblies of God, have specifically chosen not to address what they take to be social issues, such as questions surrounding the new reproductive technologies. There is no material available from such diverse groups as the Churches of Christ/Disciples of Christ, the Quakers, and the Unitarian-Universalists.

Anglican

Artificial insemination by husband and IVF using gametes from a married couple (who will also be the social parents) are morally licit. There seems to be no concern over the disposition of unused embryos in IVF. Considerable controversy surrounds the use of sperm from someone other than the husband in artificial insemination by donor and in IVF, and that issue will continue to be controversial in the near future. There is general opposition to surrogate motherhood on grounds relating to the resulting depersonalization of motherhood and to potential exploitation. This opposition would apply whether or not the surrogate mother donated the gamete or carried an implanted embryo to term (8,15,36).

Lutheran

Procreation within marriage is viewed as a positive blessing as well as a divine commandment, so the treatment of infertility is strongly encouraged. Procreative actions that take place within the general setting of a loving marital relation, even though the actual act of conception is divorced from it, are morally licit. Therefore, there is no objection to artificial insemination by husband or to IVF when it uses gametes and the womb of the married woman, and when all embryos are implanted (6,10).

Reformed (Presbyterian and United Church of Christ)

Responsible intentional procreation within marriage is viewed as religiously significant; thus medical and surgical interventions to treat infertility are generally encouraged, while contraception to avoid unintended procreation is also encouraged. There are no significant moral objections to the use of artificial insemination by husband and IVF using gametes from a married couple (regardless of whether some embryos are not used). Artificial insemination by donor and IVF using donor gametes are more controversial, but will probably be treated as morally acceptable in the context of an infertile married couple mutually and freely choosing them. Surrogate motherhood will probably be treated as illicit, in part because of psychological and relational issues and in part because of fear of abuses (26,29,30).

Methodist

Methodists insist on the connection between procreation and conjugal sexuality only in that procreation is supposed to grow out of the physical and emotional union of a married couple. Therefore, they approve of artificial insemination by husband and IVF using gametes from a married couple, especially when all embryos are implanted. They are concerned that IVF not be used for sex selection or for the creation of experimental subjects. They are opposed to artificial insemination by donor, in vitro fertilization using donor gametes, and surrogate motherhood (25,37).

Mennonite

Both the single life and married life without children are religiously acceptable lifestyles, so there is no compelling religious need for infertile couples to pursue treatment of infertility. Such treatments are appropriate, however, if they strengthen the marital relationship and marital intimacy. Since there need be no connection between acts of conjugal sexuality and reproduction, artificial insemination by husband and IVF are acceptable. Artificial insemination by donor and (presumably) surrogate motherhood are acceptable, so long as they strengthen the marital relation and marital intimacy (14,27).

Baptist

There is no necessary connection between individual procreative acts and individual acts of conjugal sexuality. Procreation is a blessing, and a biblical attitude approves of artificial attempts to make procreation possible. This justifies traditional infertility workups and treatments. It also justifies artificial insemination by husband, artificial insemination by donor, and IVF. Some Southern Baptists may, however, oppose the use of techniques involving donor gametes. Since fetuses, especially at the earliest stages, only have anticipatory personhood, abortion concerns are irrelevant to the new reproductive technologies. In light of recent Southern Baptist statements, however, some Southern Baptists may prefer limiting IVF to cases in which all embryos are transferred (5,35).

Evangelical-Fundamentalist

Although there is no absolute commandment on each individual couple to procreate, infertility is viewed in the Bible as a burden to overcome. This leads to a positive evaluation of infertility workups and treatments. In particular, because individual acts of procreation can be separated from each other, there are no moral objections to artificial insemination by husband or to IVF using gametes from a married couple. There is considerable controversy over artificial insemination by donor, IVF using donor gametes, and surrogate motherhood. Many oppose these techniques although they do not see them as adulterous. Others find them to be contemporary improvements over Biblical analogues. Recent Evangelical treatments support the former position (13,18).

Adventist

Given the legitimacy of separating individual acts of conjugal sexuality from individual acts of procreation, there are no moral objections to traditional workups and treatments of infertility and to artificial insemination by husband or IVF using gametes from a married couple. Artificial insemination by donor and IVF using donor gametes are more controversial, with some Adventists opposing them while Adventist institutions are using them. There is little support for commercialized surrogacy (19,31,32).

Christian Science

The best treatment for infertility is prayer that dispels the illusions that are the source of the problem. Individuals may choose to supplement that with techniques (e.g., artificial insemination) that employ neither drugs nor surgery, but techniques that do (including IVF) are inconsistent with the basic Christian Scientist viewpoint (38).

Jehovah's Witness

Infertility workups and traditional medical and surgical interventions are morally licit but are neither encouraged nor discouraged because no particular moral significance is ascribed to parenthood. Artificial insemination by husband is morally licit, as is IVF providing that the gametes come from the married couple, no zygotes are destroyed, and no blood products are used. Artificial insemination by donor, surrogate motherhood, and IVF (if the above conditions are not satisfied) are serious violations of some of God's fundamental laws (39).

Mormon Church

Because of their great emphasis on procreation, Mormons encourage infertility workups, traditional medical and surgical interventions, and accept artificial insemination and IVF using gametes from the married couple. While not encouraged, artificial insemination by donor is left as an option for couples. Surrogate motherhood and artificial insemination of single women are opposed. Though not explicitly addressed, the disposal of nonimplanted embryos in IVF would be problematic for many Mormons, as potentially a form of abortion (4,28).

Jewish

Because of the religious and personal significance of procreation, traditional infertility workups and treatments are encouraged, subject to the constraint of minimizing the use of masturbation. Artificial insemination by husband is acceptable, as is IVF when it uses gametes from a married couple and when all embryos are implanted. Artificial insemination by donor and IVF using gametes from a third party are more controversial. They are acceptable to Reform Judaism and are increasingly acceptable as a last alternative to Conservative Judaism, but are rejected by Orthodox Judaism (2,11,17,20).

Islamic

Because of the great significance of reproduction, Islam welcomes effective infertility workups and treatments and would not be troubled by use of masturbation. Muslims would have no problems with artificial insemination by husband and with IVF when both gametes come from a married couple and when all embryos are implanted. Artificial insemination by donor and IVF using donor sperm would be rejected on the grounds that they confuse lineage, and they might also be rejected as forms of adultery. A failure to implant all embryos in IVF might be prohibited (although not strongly) as a form of early abortion (1,33).

Other Religious Traditions

An increasing number of Asian-Americans have viewpoints rooted in such religions as Hinduism, Buddhism, and Confucianism. These are old and rich traditions, with extensive views on human sexuality, reproduction, nature, and technology. There is no evidence, however, that contemporary scholars in these traditions are attempting to apply their views to the topic of reproductive technologies.

A great many religious communities in the United States grow out of the Afro-American experience. They range in size from major segments of the Methodist and Baptist traditions to santeria and voodoo centers. No written material is available on what these religious groups think about the new reproductive technologies. In particular, it is not clear whether general Methodist and Baptist viewpoints would be equally shared by the major black Methodist and Baptist churches.

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Appendix G

OTA Survey of Surrogate Mother Matching Services

As part of this assessment, OTA identified the following surrogate mothering matching services around the country (see box 14-B):

California

Hilary Hanafin and William Handel
Center for Surrogate Parenting
8383 Wilshire Boulevard
Beverly Hills, CA 90211

Nina Kellogg
Surrogate Parent Program
11110 Ohio Avenue, Suite 202
Los Angeles, CA 90025

Bruce Rappaport
Center for Reproductive Alternatives of
Northern California
3313 Vincent Road, Suite 222
Pleasant Hills, CA 94523

Bernard A. Sherwyn
10880 Wilshire Boulevard
Suite 614
Los Angeles, CA 90024

Katherine Wycoff
Center for Reproductive Alternatives
727 Via Otono
San Clemente, CA 92672

Georgia

Debra A. Patton
Infertility Alternatives
P.O. Box 1084
Snellville, GA 30278

Indiana

Steven Litz
Surrogate Mothers, Inc.
2612 McLeay Drive
Indianapolis, Indiana 46220

Kansas

Beth Bacon
Hagar Institute
1015 Buchanan
Topeka, KS 66604

Kentucky

Katie Marie Brophy
Surrogate Family Services Inc.
713 W. Main Street
Suite 400
Louisville, KY 40202

Richard Levin
Surrogate Parenting Associates
250 East Liberty Street, Suite 222
Louisville, KY 40202

Maryland

Harriet Blankfeld
Infertility Associates International
5530 Wisconsin Avenue, Suite 940
Chevy Chase, MD 20815

Michigan

Noel Keane
930 Mason
Dearborn, MI 48124

Nevada

Juanita Lewis
Surrogate Mother, Inc.
620 Lander Street, Suite 2A
Reno, NV 89509

New York

Betsy Aigen
Surrogate Mother Program
Suite 3D
640 West End Avenue
New York, NY 10024

Ada D. Greenberg
Surrogate Pregnancy Consultations
P.O. Box 52
Jamaica, NY 11415-6052

Infertility Center of New York
14 East 60th Street, Suite 1204
New York, NY 10022

Oregon

Norma Thorsen
Surrogate Foundation, Inc.
P.O. Box 6545
Portland, OR 97206

Of 27 services contacted, 5 were no longer in business, 5 had moved with no forwarding address, 4 failed to respond, and 13 returned completed questionnaires. For the 2 nonrespondents, data were collected by examining the contracts they have used in the past, the testimony of their directors at congressional hearings, in their own published writings, and their interviews with the press.

The following are the questions asked on the survey questionnaire. For the purposes of this survey, "client" referred to the person who wishes to hire a surrogate mother. "Client's spouse/partner" referred to the person with whom the client intends to rear the child. "Surrogate mother" referred to a woman who is artificially inseminated with the intention of relinquishing custody upon birth to the genetic father. With the exception of question (27), this survey did not concern "surrogate gestational mothers," i.e. women who bear children to whom they are not genetically related.

NATIONAL SURVEY OF SURROGATE MOTHER MATCHING SERVICES

OPTIONAL IDENTIFICATION

Your completion of this page allows us to know which organizations have responded to the survey.

Please detach this page and return it separately, so that your agency's name cannot be matched to your response. A self-addressed, postage paid envelope is enclosed for your convenience.

Of course, we are also happy to receive your response to the survey without your having completed this section at all.

ORGANIZATION NAME ....

ADDRESS ....

....

....

....

TELEPHONE ....

NATIONAL SURVEY OF SURROGATE MOTHER MATCHING SERVICES

This is a survey of surrogate matching services in the United States. The results of this survey will be used in the assessment **Infertility Prevention and Treatment**, being prepared by the Office of Technology Assessment upon the request of Congress. Your participation is greatly appreciated.

For the purposes of this survey, "client" refers to the person who wishes to hire a surrogate mother. "Client's spouse/partner" refers to the person with whom the client intends to rear the child. Please answer all questions concerning demographics by reference to the client and not the client's spouse or partner. "Surrogate mother" refers to a woman who is artificially inseminated with the intention of relinquishing custody upon birth to the genetic father. With the exception of question (27), this survey does not concern "surrogate gestational mothers," i.e. women who bear children to whom they are not genetically related.

DEMOGRAPHICS OF YOUR AGENCY

1. Location:
   - __ major metropolitan area
   - __ smaller city
   - __ suburb
   - __ rural area

2. Size and professional qualifications of staff:

   ____

   ____

   ____

   ____

3. Are you affiliated with:

	Yes	No
a hospital?	__	__
a physician's practice?	__	__
an infertility clinic?	__	__
a law firm?	__	__
other?		

(specify) ____

4. Year of first matching arrangement: ____

5. How many matches have you made:

since you opened?	__
in 1986?	__
in 1987?	__

6. How many babies have been born as a result:

since you opened? ___
in 1986? ___
in 1987? ___

7. How many matches do you predict you will arrange per year:

in 1988? ___
5 years from now? ___
10 years from now? ___

8. How many clients and surrogate mothers are currently seeking the services of your agency?

Clients ___
Surrogates ___

9. Do you perceive any recent change in the number of inquiries from prospective clients or prospective surrogates, perhaps as a result of the Baby M case?

	Increase	Decrease	No change
Clients	___	___	___
Surrogates	___	___	___

10. How are potential clients and surrogates attracted to your agency? If possible, please rank in order of frequency (1 for most frequent, 2 for next most frequent, etc.).

	Clients	Surrogates
a) Word of mouth	___	___
b) Direct solicitation	___	___
c) Advertisement	___	___
If so, by what medium?	___	
d) Other (specify)	___	

11. Have you ever matched clients and surrogate mothers:

	Yes	No
a) from different states?	___	___
b) from different countries?	___	___
c) from different religions?	___	___
d) from different ethnic groups?	___	___
e) from different races?	___	___

SCREENING CLIENTS

12. Have you ever offered to find a surrogate mother for a client who is:

	Yes	No	Would if asked
a) an unmarried woman	___	___	___
b) an unmarried man	___	___	___
c) an unmarried couple	___	___	___
d) a homosexual man	___	___	___
e) a homosexual woman	___	___	___

13. Do you require that the person seeking to hire a surrogate mother:

	Client		Client's Partner	
	Yes	No	Yes	No
a) be in good health	___	___	___	___
b) be fertile	___	___	___	___
c) be infertile	___	___	___	___
d) be within a certain age range (specify)	___	___	___	___
e) have a minimum income (specify)	___	___	___	___
f) other (specify)	___	___	___	___

14. Do you require that clients and their spouses/partners undergo:

	Client		Client's Partner	
	Yes	No	Yes	No
a) Home review	___	___	___	___
b) Physical examination	___	___	___	___
c) STD testing	___	___	___	___
d) Psychological examination	___	___	___	___

If yes: what type? ___
by whom? ___
where are professional services obtained? ___

e) Other exam ___

SCREENING SURROGATES

15. Which of the following do you require of the person seeking to be a surrogate mother?

	Yes	No
a) be heterosexual	___	___
b) be in a stable relationship	___	___
c) be married	___	___
d) be in good health	___	___
e) have a prior conception	___	___
f) have a prior birth	___	___
g) have previously given up a child for adoption	___	___
h) have previously given up a child as a surrogate mother	___	___
i) be within a certain age range (specify)	___	___
j) have a minimum income (specify)	___	___

k) other (specify) ___

16. Do you require that surrogates and their partners undergo:

	Surrogate		Surrogate's Partner	
	Yes	No	Yes	No
a) Home review	___	___	___	___
b) Physical examination	___	___	___	___
c) Psychological examination	___	___	___	___

If yes: what type? ___
by whom? ___
where are professional services obtained? ___

d) Other exam ___

17. Do you allow clients to choose a surrogate mother on the basis of:

	Yes	No
a) physical characteristics	___	___
b) ethnic origin	___	___
c) race	___	___
d) religion	___	___

18. Do you allow clients and surrogates to:

	Yes	No	If yes, when? (before or after conception, birth)
a) know each other's names and addresses?	___	___	___
b) meet each other?	___	___	___
c) have periodic contact during pregnancy?	___	___	
d) have contact after birth?	___	___	

USE OF PROFESSIONALS

19. Where do surrogates and clients obtain legal advice?

	Surrogates		Clients	
	Yes	No	Yes	No
a) We have in-house attorneys	___	___	___	___
b) We refer to attorneys	___	___	___	___
c) Must obtain attorneys on their own	___	___	___	___

20. Does the same attorney ever represent both parties? Yes _ No _
If yes, under what circumstances? ___

21. Where do surrogates and clients obtain psychological advice?

	Surrogates		Clients	
	Yes	No	Yes	No
a) We have in-house mental health professionals	___	___	___	___
b) We refer to mental health professionals	___	___	___	___
c) Must obtain mental health professionals on their own	___	___	___	___

22. Is the use of mental health professionals or other support groups:

	Surrogates		Clients	
a) mandatory before signing a contract?	___	___	___	___
b) mandatory during pregnancy?	___	___	___	___
c) mandatory after the birth?	___	___	___	___

23. Where do surrogates and clients obtain medical services?

	Surrogates		Clients	
	Yes	No	Yes	No
a) We have in-house physicians	___	___	___	___
b) We refer to physicians	___	___	___	___
c) Must obtain physicians on their own	___	___	___	___
d) Client obtains physician for surrogate	___	___		

CONTRACTS

24. Do you provide a standard contract? Yes ___ No ___

25. What are your most typical contract provisions? Please comment on the following possible provisions and any others not mentioned. If you have a standard contract, please enter its provisions. If not, enter those which are most typical. We would appreciate receiving a copy of the typical contract(s) if possible.

a) Does the contract provide that the client has any authority to make decisions concerning:

	Yes	No
(1) a chorionic villus biopsy?	___	___
(2) an amniocentesis?	___	___
(3) termination of pregnancy?	___	___
(4) prenatal care?	___	___
(5) use of prescription medicine?	___	___

b) Are any of the following prescribed or proscribed in the contract:

	Prescribed	Proscribed	No mention
(1) Diet?	___	___	___
(2) Exercise?	___	___	___
(3) Cigarettes?	___	___	___
(4) Alcohol?	___	___	___
(5) Marijuana?	___	___	___
(6) Other illegal drugs?	___	___	___
(7) Surrogate agrees to follow doctor's orders?	___	___	___
(7) Other (please specify)?			

____

____

c) Does your contract state that:

	Yes	No
(1) the surrogate will relinquish custody at birth?	___	___
(2) the surrogate will terminate her parental rights prior to birth?	___	___
(3) the surrogate will terminate her parental rights upon birth?	___	___
(4) the client will accept the child regardless of gender?	___	___
(5) the client will accept the child regardless of health?	___	___
(6) the client will accept the child regardless of health unless the problem is due to surrogate's carelessness or breach of contract?	___	___
(7) the client's partner will accept the child if the client falls ill or dies?	___	___

d) What remedies are listed in the contract in the event that:

(1) the surrogate fails to abide by a life-style restriction?

____

____

(2) the surrogate fails to follow her doctor's advice?

____

____

(3) the surrogate fails to relinquish custody?

____

____

(4) the surrogate fails to relinquish parental rights?

____

____

(5) the client fails to accept the child?

____

____

(6) the client fails to pay?

____

____

(7) the client and partner die before birth or finalization of adoption?

____

____

e) What are the fees paid to the surrogate in the event of:

(1) failure to become pregnant? ___
(2) miscarriage? ___
(3) terminated pregnancy? ___
(4) stillbirth? ___
(5) birth of child with health problems? ___
(6) birth of healthy child? ___

f) What other fees and deposits are specified?

	How much?	Paid by whom?	Paid when?
(1) Fees to attorneys	___	___	___
(2) Fees to psychiatrists	___	___	___
(3) Fees to physicians for prenatal care	___	___	___
(4) Fees to your agency	___	___	___
(5) Deposits in escrow accounts	___	___	___

(6) Other (specify) ____

26. Have your agency, your clients, or your surrogates ever been threatened with litigation? If yes, please give an estimate of the number of cases dropped, settled, or pending.

___

___

___

___

___

OTHER SERVICES

27.

	Yes	No
a) Do you offer preconception sex selection?	___	___
b) Do you offer surrogate embryo transfer?	___	___
c) Do you offer artificial insemination by donor?	___	___
d) Do you match clients and surrogate gestational mothers, ie women who carry a child to whom they are not genetically related?	___	___

If the answer to (d) is yes, are any of the above screening, counseling, contract or fee provisions different? Please specify.

___

___

___

___

___

___

DEMOGRAPHICS OF CLIENTS

(if no precise data, use best guess)

28. Age: Range ___ Average (best estimate) ___

29. Marital status:
- Married: ___ percent
- Unmarried couple: ___ percent
- Single: ___ percent

30. Sexual orientation:
- Heterosexual: ___ percent
- Homosexual: ___ percent
- Bisexual: ___ percent

31. Religion (please give best estimate of percentages, or rank in perceived frequency):
- Catholic ___
- Protestant (fundamentalist) ___
- Protestant (all other) ___
- Jewish ___
- Muslim ___
- Other ___
- Unknown ___

32. Race (please give best estimate of percentages, or rank in perceived frequency):
- White ___
- Black ___
- Asian ___
- Other ___

33. How many already have a child? ___

34. Reasons clients cite for seeking a surrogate mother (please rank in order of frequency):

___

___

___

___

35. Economic status of those seeking a surrogate mother (please give best estimate of percentages, or rank in perceived frequency):
- family income below $15,000: ___
- between 15,000 and 30,000: ___
- between 30,000 and 50,000: ___
- above 50,000: ___

36. Educational status:
- High school: ___ percent
- College: ___ percent
- Graduate degree: ___ percent

DEMOGRAPHICS OF SURROGATES

37. Age: Range ____ Average (best estimate) ____

38. Marital status:
    Married: ____ percent
    Unmarried couple: ____ percent
    Single: ____ percent

39. Sexual orientation:
    Heterosexual: ____ percent
    Homosexual: ____ percent
    Bisexual: ____ percent

40. Religion (please give best estimate of percentages, or rank in perceived frequency):
    Catholic ____
    Protestant (fundamentalist) ____
    Protestant (all other) ____
    Jewish ____
    Muslim ____
    Other ____
    Unknown ____

41. Race (please give best estimate of percentages, or rank in perceived frequency):
    White ____
    Black ____
    Asian ____
    Other ____

42. Reasons cited for seeking to be a surrogate mother (please rank in order of frequency):

43. Economic status of those offering to be a surrogate mother (please give best estimate of percentages, or rank in perceived frequency):

    family income below $15,000: ____
    between 15,000 and 30,000: ____
    between 30,000 and 50,000: ____
    above 50,000: ____

44. Educational status:
    High school: ____ percent
    College: ____ percent
    Graduate degree: ____ percent

45. Percentage who:

    a) have had a prior pregnancy: ____
    b) have had a miscarriage: ____
    c) have had an abortion: ____
    d) have relinquished a previous child for adoption: ____
    e) have relinquished a child as a surrogate: ____
    f) are themselves adopted: ____

OPINION

46. What do you think of the Baby M decision?

47. Do you think there is any role for professional societies with respect to surrogate mothering practice? Yes ___ No ___

    If not, why not?

    If so, precisely what would you like to see done?

48. Do you think there is any role for state government with respect to surrogate mothering practice? Yes ___ No ___

    If not, why not?

    If so, precisely what would you like to see done?

49. Do you think there is any role for the federal government with respect to surrogate mothering practice? Yes ___ No ___

    If not, why not?

    If so, precisely what would you like to see done?

Please feel free to attach further comments.

Appendix H

List of Contractor Documents

For this assessment, OTA commissioned reports on various topics concerning infertility prevention and treatment. The manuscripts of 10 of these contractor documents are available in four volumes from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA, 22161; (703) 487-4650.

Volume I: Research

"Animal Reproductive Technologies and Their Potential Applications for Human Fertility Problems: A Review," Robert A. Godke, Department of Animal Science, Louisiana State University, Baton Rouge, LA.

"Frontiers of Reproductive Research," Richard P. Marrs, Division of Reproductive Endocrinology and Infertility, Cedars-Sinai Medical Center, Los Angeles, CA.

Volume II: Prevention of Infertility

"A Report on a Proposed Method To Prevent Infertility: Self-Identification of Risk for Infertility," Michael R. Soules, Division of Reproductive Endocrinology, Department of Obstetrics and Gynecology, University of Washington, Seattle, WA.

"Prevention of Infertility," James A. McGregor, Department of Obstetrics and Gynecology, University of Colorado Health Sciences Center, Denver, CO.

Volume III: Economics of Infertility

"Economic Considerations for Infertility: Third Party Coverage of Infertility Treatments," Charles P. Hall, Jr., and Arnold Raphaelson, School of Business and Management, Temple University, Philadelphia, PA.

"Expenditures on Infertility Treatment," Emanuel Thorne and Gilah Langner, Washington, DC.

Volume IV: Social and Medical Concerns

"Psychological Aspects of Being Infertile," Constance H. Shapiro, Department of Human Service Studies, New York State College of Human Ecology, Cornell University, Ithaca, NY.

"Religious and Secular Perspectives About Infertility Prevention and Treatment," Baruch A. Brody, Baylor College of Medicine, Center for Ethics, Medicine, and Public Issues, Houston, TX.

"Risks of Infertility and Diagnosis and Treatment," Helen Bequaert Holmes, Women's Research College, Hartford College, Amherst, MA.

"Risks of Infertility Diagnosis and Treatment," Anthony R. Scialli, Reproductive Toxicology Center, Columbia Hospital for Women, Washington, DC.

Appendix I

Acknowledgments

OTA would like to thank the members of the advisory panel who commented on drafts of this report, the contractors who provided material for this assessment, and the many individuals and organizations that supplied information for the study. In addition, OTA acknowledges the following individuals for their review of drafts of this report:

C.F.D. Ackman
Montreal, Canada

G. David Adamson
Palo Alto, CA

Angeles Tan Alora
University of the Philippines

Cynthia Alpert
Arlington, VA

Donna Day Baird
National Institute of Environmental Health Sciences

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Health and Welfare Services, Canada

Ditta Bartels
University of New South Wales, Australia

Jonathan Van Blerkom
University of Colorado at Boulder

Baruch A. Brody
Baylor College of Medicine

Kathy J. Bryant
American College of Obstetricians and Gynecologists

Martin Büechi
Embassy of Switzerland

Lester Bush
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Maria Bustillo
Fairfax-Northern Virginia Genetics and IVF Institute

M. Christian Byk
Ministere la Justice, France

A. Campana
Ospedale Distrettuale (La Carita), Switzerland

Willard Cates, Jr.
Centers for Disease Control

Paolo Cattorini
Milano, Italy

Wendy Chavkin
New York City Department of Health

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Glinda S. Cooper
Uniformed Services University of the Health Sciences

A. Costoya
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Carolyn B. Coulam
Methodist Center for Reproduction and Transplantation Immunology

B. Courvoisier
Swiss Academy of Medical Science

Thomas Vincent Daly
St. Vincent's Bioethics Center, Australia

Marian D. Damewood
The Johns Hopkins Hospital

Ken Daniels
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Miriam Davis
U.S. Department of Health and Human Services

David M. de Kretser
Monash University, Australia

Bernard M. Dickens
University of Toronto

Laneta J. Dorflinger
U.S. Agency for International Development

Richard J. Dowling
Maryland Catholic Conference

Rebecca S. Dresser
Baylor College of Medicine

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Jacqueline Darroch Forrest
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Mark S. Frankel
American Association for the Advancement of Science

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Law Reform Commission of Canada

Allan R. Glass
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Mohsen Ahmed Khairy
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Attaché for Health and the Environment, Royal Netherlands Embassy

Edmund Meuwissen
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Virginia Michaels
Mayo Clinic

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Jacques E. Rioux
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John A. Robertson
University of Texas at Austin

Robert C. Robinson
National Conference of Commissioners on Uniform State Laws

Robyn Rowland
Deakin University, Australia

Suzanne Sangree
American Civil Liberties Union Foundation

Hans-Martin Sass
Ruhr University, Federal Republic of Germany

D.M. Saunders
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Phillip E. Schambra
U.S. Science Attaché in India

J.G. Schenker
Hadassah University Hospital, Jerusalem

Steven M. Schrader
National Institute for Occupational Safety and Health

Amos Shapira
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Appendix J

Glossary of Acronyms and Terms

Glossary of Acronyms

AATB	—American Association of Tissue Banks
ACOG	—American College of Obstetricians and Gynecologists
AFDC	—Aid to Families with Dependent Children (DHHS)
AFS	—American Fertility Society
AGI	—Alan Guttmacher Institute
AI	—artificial insemination
AIDS	—acquired immunodeficiency syndrome
AMA	—American Medical Association
BBT	—basal body temperature
BC/BS	—Blue Cross/Blue Shield Associations
CAHBI	—Ad Hoc Committee of Experts on Progress in the Biomedical Sciences (Council of Europe)
CC	—clomiphene citrate
CCNE	—Comité Consultatif National d'Ethique (National Advisory Ethics Committee) (France)
CDC	—Centers for Disease Control (PHS, DHHS)
CECOS	—Centres d'Etude et de la Conservation du Sperme (Centers for the Study and Conservation of Sperm) (France)
CFR	—Code of Federal Regulations
CHAMPUS	—Civilian Health and Medical Program of the Uniformed Services (U.S. Department of Defense)
CHAMPVA	—Civilian Health and Medical Program of the Veterans' Administration (VA)
CMV	—cytomegalovirus
CNFA	—Comisión Nacional de Fecundación Asistida (National Commission on Assisted Reproduction) (Spain)
CON	—certificate of need
DES	—diethylstilbestrol
DHHS	—U.S. Department of Health and Human Services
DNA	—deoxyribonucleic acid
EAB	—Ethics Advisory Board
FDA	—Food and Drug Administration (PHS, DHHS)
FEHB	—Federal Employees Health Benefits Plan
FINRRAGE	—Feminist International Network of Resistance to Reproductive and Genetic Engineering
FSH	—follicle-stimulating hormone
FTC	—U.S. Federal Trade Commission
GIFT	—gamete intrafallopian transfer
GnRH	—gonadotropin releasing hormone
hCG	—human chorionic gonadotropin
HIV	—human immunodeficiency virus
hMG	—human menopausal gonadotropin
HMO	—health maintenance organization
HSG	—hysterosalpingogram
IEC	—Institutional Ethics Committee (Australia)
INSERM	—Institut National de la Santé et de la Recherche Médicale (National Health and Medical Research Institute) (France)
IRB	—Institutional Review Board
IUD	—intrauterine device
IVF	—in vitro fertilization
JCAHO	—Joint Commission on Accreditation of Healthcare Organizations
LH	—luteinizing hormone
LH-RH	—luteinizing hormone-releasing hormone
LPD	—luteal phase defect
MREC	—Medical Research Ethics Committee (Australia)
NCHS	—National Center for Health Statistics (DHHS)
NHMRC	—National Health and Medical Research Council (Australia)
NIH	—National Institutes of Health (PHS, DHHS)
NMCUES	—National Medical Care Utilization and Expenditure Survey
NPT	—nocturnal penile tumescence
NSFG	—National Survey on Family Growth (NCHS, DHHS)
OHSS	—ovarian hyperstimulation syndrome
OHTA	—Office of Health Technology Assessment (PHS, DHHS)
OTA	—Office of Technology Assessment
PHS	—U.S. Public Health Service (DHHS)
PID	—pelvic inflammatory disease
POD	—polycystic ovarian disease
ProPAC	—Prospective Payment Assessment Commission (U.S. Congress)
PTSD	—post-traumatic stress disorder
PVA	—Paralyzed Veterans of America

SLA —Statutory Licencing Authority (U.K.)
STD —sexually transmitted disease
TEC —Technology Evaluation and Coverage Program (BC/BS)
UCC —Uniform Commercial Code
VA —U.S. Veterans' Administration
VLA —Voluntary Licencing Authority (U.K.)

Glossary of Terms

Adhesions: Rubbery bands of scar tissue (usually caused by previous infections or surgery) attached to organ surfaces, capable of connecting, covering, or distorting organs such as the fallopian tubes, ovaries, or bowel. Adhesions in the fallopian tubes and ovaries obstruct the movement of sperm and oocytes.

Agglutinization of sperm: The binding together of sperm in clumps.

Amenorrhea: The absence of menstruation.

Anovulation: The absence of ovulation.

Antibody: A blood protein (immunoglobin) produced by white blood cells in response to the presence of a specific foreign substance (antigen) in the body, with which it fights or otherwise interacts. Antibodies to sperm, if present, can impair fertility by causing agglutination of sperm.

Artificial insemination (AI): The introduction of sperm into a woman's vagina or uterus by noncoital methods, for the purpose of conception.

Azoospermia: The absence of sperm in the semen.

Basal body temperature (BBT): A woman's resting temperature upon awakening in the morning before any activity; the temperature rises slightly when ovulation occurs and remains at the higher level until the next menstruation. Recording and charting BBT is one of the oldest and most popular methods for predicting ovulation.

Blastocyst: A fluid-filled sphere of cells developed from a zygote. The embryo develops from a small cluster of cells in the center of the sphere, and the outer wall of the sphere becomes the placenta. The blastocyst, also called a preimplantation embryo, begins to implant into the lining of the uterus 6 to 7 days after fertilization.

Breach of contract: A party's failure to perform a contractually agreed-upon act.

Bromocriptine: A synthetic compound that interferes with the pituitary gland's ability to secrete prolactin. Bromocriptine is often prescribed for hyperprolactinemia.

Certificate of need (CON): A regulatory planning measure established by the National Health Planning Resources Development Act of 1974 to help State and local health planning agencies review capital expenditure applications from institutions, and to explore other ways of reducing medical costs.

Cervical mucus: Mucus produced by the cervix that undergoes complex changes in its physical properties in response to changing hormone levels during the reproductive cycle. These changes assist the survival and transport of sperm.

Chimera: An individual consisting of cells or tissues of diverse genetic constitution (e.g., from different species).

Chlamydia: An STD caused by the bacteria *Chlamydia trachomatis*. In women, chlamydial infection accounts for 25 to 50 percent of the pelvic inflammatory disease cases seen each year. Chlamydia is the most common STD in the United States today.

Choice-of-law: Body of law by which a court determines which State or country's laws ought to apply to the case before the court.

Chromosomal abnormalities: Genetic mutations involving changes in the number and structure of chromosomes. This can affect fertility through early fetal loss caused by genetic factors, impairment in the reproductive function in an adult caused by chromosomal abnormalities already present, or by genetic predisposition toward certain diseases, such as endometriosis.

Chromosome: A rod-shaped body in a cell nucleus that carries the genes that convey hereditary characteristics.

Cleavage: The stage of cell division that takes place immediately after fertilization and that lasts until the cells begin to segregate and differentiate and to develop into a blastocyst.

Clomiphene citrate (CC): A nonsteroidal estrogen-like compound that binds to estrogen receptors in the body. CC is a commonly prescribed fertility drug, primarily used in patients with oligomenorrhea to promote increased gonadotropin secretion and stimulation of the ovary.

Conceptus: The mass of cells resulting from the earliest stages of cell division of a zygote.

Confidentiality: A fundamental component of the physician-patient relationship, stemming primarily from the Hippocratic oath, in which the physician has the duty to keep confidential all that is confided by the patient.

Consensus conference: A meeting of experts held under the auspices of the NIH Consensus Development Program (established in 1977), to develop consensus on the clinical application of new medical findings.

Corpus luteum: A gland that forms on the surface of the ovary at the site of ovulation and produces progesterone during the second half of the menstrual cycle, in order to prepare the uterus for a possible pregnancy. The corpus luteum regresses if pregnancy does not occur.

Cryopreservation: The preservation of sperm, embryos, and oocytes by freezing them at extremely low temperatures.

Cryptorchidism: Undescended testes.

Damages: Monetary compensation that the law awards to a person who has been injured by the actions of another.

Danazol: A synthetic derivative of testosterone used in the treatment of endometriosis.

Diagnostic tests: Tests performed to evaluate reproductive health. In women, this can involve indirect indicators (menstrual irregularity, hormone levels, cervical mucus) and direct ones (tissue biopsy, laparoscopy, ultrasound). In men, tests include semen analysis, endocrine evaluation, testicular biopsy, and evaluation of sexual dysfunction.

Dictum (pl. dicta): A statement or observation in a judicial opinion that is not necessary for the decision on the case. Dictum differs from a "holding" in that it is not binding on the courts in subsequent cases.

Deoxyribonucleic acid (DNA): The nucleic acid in chromosomes that codes for genetic information.

Donor gametes: Eggs or sperm donated by individuals for medically assisted conception.

Ectopic pregnancy: A pregnancy that occurs outside the uterus, usually in a fallopian tube.

Ejaculation: A two-part spinal reflex that involves emission, when the semen moves into the urethra, and ejaculation proper, when it is propelled out of the urethra at the time of orgasm.

Electroejaculation: Electrical stimulation of the nerve that controls ejaculation, used to obtain semen from men with spinal cord injuries.

Embryo: Term used to describe the stages of growth from the second to the ninth week following conception. During this period cell differentiation proceeds rapidly and the brain, eyes, heart, upper and lower limbs, and other organs are formed.

Embryo donation: The transfer from one woman to another of an embryo obtained by artificial insemination and lavage or, more commonly, by IVF.

Embryo lavage: A flushing of the uterus to recover a preimplantation embryo.

Embryo transfer: The transfer of an in vitro fertilized egg from its laboratory dish into the uterus of a woman.

Endometrial biopsy: The microscopic examination of a sample of cells, obtained from the lining of the uterus between days 22 and 25 of a normal 28-day menstrual cycle, in order to evaluate ovulatory function.

Endometriosis: The presence of endometrial tissue (the normal uterine lining) in abnormal locations such as the fallopian tubes, ovaries, or the peritoneal cavity. Endometriosis can interfere with nearly every phase of the reproductive cycle and is a leading contributor to infertility in women. The causes and development of endometriosis are incompletely understood.

Endometrium: The tissue lining the uterus.

Epididymis: A coiled tubular structure in the male that receives sperm moving from the testis to the vas deferens. Sperm are stored and matured for a period of several weeks in the epididymis.

Epididymitis: Infection of the epididymis, usually from an STD, such as gonorrhea, that can impair fertility during the course of the infection, as well as causing scarring that can partially or completely block sperm transport.

Estrogen: A class of steroid hormones, produced mainly by the ovaries from puberty to menopause.

Ethics Advisory Board: Established within the Department of Health, Education, and Welfare to review proposals for Federal funding of research involving IVF. The Ethics Advisory Board ceased to function in 1980.

Experimental technology or treatment: A technology or treatment the safety and efficacy of which has not been established.

Extracorporeal embryo: An embryo maintained outside the body.

Fallopian tube: Either of a pair of tubes that conduct the egg from the ovary to the uterus. Fertilization normally occurs within this structure. Blocked or scarred fallopian tubes are a leading source of infertility in women.

Fecund: Able to conceive. A characterization used by demographers to identify couples who have no known physical problem that prevents conception.

Fern test: Evaluation of fern-like pattern of dried cervical mucus. As ovulation approaches, more ferning can be observed.

Fertility drugs: Compounds used to treat ovulatory dysfunction. These include clomiphene citrate, human gonadotropins, bromocriptine, glucocorticoids, and progesterone.

Fertilization: The penetration of an oocyte by a sperm and subsequent combining of maternal and paternal DNA.

Fetus: The embryo becomes a fetus after approximately 9 weeks in the uterus. This stage of development lasts from 9 weeks until birth and is marked by the growth and specialization of organ function.

Fimbria: The fringed entrance to the fallopian tubes.

Fimbrioplasty: A surgical procedure to correct partial restriction of the fallopian tube.

First Amendment: The First Amendment to the U.S. Constitution. It guarantees freedom of speech, press, assembly, petition, and exercise of religion.

Follicle: The structure on the ovary surface that nurtures a ripening oocyte. At ovulation the follicle ruptures and the oocyte is released. The follicle produces estrogen until the oocyte is released, after which it becomes a yellowish protrusion on the ovary called the corpus luteum.

Follicle-stimulating hormone (FSH): A pituitary hormone, also known as a gonadotropin, that along with other hormones stimulates hormone and gamete production by the testes and ovaries.

Fourteenth Amendment: The Fourteenth Amendment to the U.S. Constitution. It guarantees due process of law and equal protection of the law. The latter has come to mean that the States and Federal Government may not discriminate without at least a rational purpose and, at times, without a compelling purpose.

Fundamental right: A right not enumerated in the U.S. Constitution but deemed so apparent from examination of the Constitution and Declaration of Independence or other sources that it is protected from undue interference by Federal or State action. The right to marry, for example, has been deemed a fundamental right.

Gamete: A reproductive cell. In a man, the gametes are sperm; in a woman, they are eggs, or ova.

Gamete intrafallopian transfer (GIFT): A technique of medically assisted conception in which mature oocytes are surgically removed from a woman's body and then reintroduced, together with sperm, through a catheter threaded into the fallopian tubes, where it is hoped fertilization will take place.

Gene: The portion of a DNA molecule that consists of an ordered sequence of nucleotide bases and constitutes the basic unit of heredity.

Glucocorticoids: Hormones naturally produced by the adrenal glands. Synthetic glucocorticoids are used to treat ovulatory dysfunction caused by adrenal disorders.

Gonad: Ovary or testis.

Gonadotropin: Hormone that stimulates the testes or ovaries. Examples are follicle-stimulating hormone, human chorionic gonadotropin, human menopausal gonadotropin, and luteinizing hormone. These can be administered in cases of ovulatory dysfunction to directly stimulate the ovary.

Gonadotropin releasing hormone (GnRH): The hormone released from the hypothalamus that causes secretion of gonadotropins from the pituitary gland.

Gonorrhea: An STD caused by the bacteria *Neisseria gonorrheae*. If the infection is not treated in women, it can spread to the uterus and the fallopian tubes, causing PID. In men, it can cause epididymitis and can affect semen quality.

Hamster-oocyte penetration test: A test that evaluates the ability of human sperm to penetrate an ovum by incubating sperm with hamster oocytes that have had their outer layer removed. Normal sperm will penetrate the eggs. The reliability and significance of this test are controversial.

Health maintenance organization (HMO): A health care organization that serves as both insurer and provider of comprehensive but specified medical services, provided by a defined group of physicians to an enrolled, fee-paying population.

Human chorionic gonadotropin (hCG): A hormone secreted by the embryo that maintains the corpus luteum when pregnancy occurs. This hormone can be extracted from the urine of pregnant women and can be injected to stimulate ovaries and testes.

Human menopausal gonadotropin (hMG): Hormone that can be extracted from the urine of menopausal women and injected to stimulate ovaries and testes.

Hyperprolactinemia: The overproduction of the pituitary hormone prolactin, which can contribute to infertility. The causes of this condition are diverse and poorly understood. It can be treated with bromocriptine.

Hypospadias: A structural abnormality of the penis caused by an opening on the underside.

Hypothalamus: A structure at the base of the brain that controls (among other things) the action of the pituitary gland. By secreting and releasing hormones, the hypothalamus orchestrates the body's reproductive function in both men and women.

Hysterosalpingogram: An x-ray study of the female reproductive tract in which dye is injected into the uterus while x rays are taken showing the outline of the uterus and the degree of openness of the fallopian tubes.

Hysteroscopy: Direct visualization of the interior of the uterus in order to evaluate any abnormalities that may be present. This is done by inserting a hysteroscope (a long, narrow, illuminated tube) through the cervix into the expanded uterus. Surgical procedures may also be performed using this method.

Iatrogenic: Resulting from the action of physicians. The term is commonly applied to diseases or disabilities caused by medical care.

Idiopathic: Of unknown origin.

Impaired fecundity: Categorization of infertility used by demographers to describe couples who are nonsurgically sterile, or for whom it would be difficult or dangerous to have a baby.

Impotence: The inability to achieve or maintain an erection.

Implantation: The process by which the fertilized oocyte (zygote) becomes attached to the wall of the uterus (endometrium).

In vitro: Literally "in glass"; pertaining to a biological process or reaction taking place in an artificial environment, usually a laboratory.

In vitro fertilization (IVF): A technique of medically assisted conception (sometimes referred to as "test tube" fertilization) in which mature oocytes are removed from a woman's ovary and fertilized with sperm in a laboratory. (See *embryo transfer*.)

In vivo: Literally "in the living"; pertaining to a biological process or reaction taking place in a living cell or organism.

In vivo fertilization: The fertilization of an egg by a sperm within a woman's body. The sperm may be introduced by artificial insemination or by coitus.

Infertility: Inability of a couple to conceive after 12 months of intercourse without contraception.

Intracervical insemination: Artificial insemination technique in which sperm are placed in or near the cervical canal of the female reproductive tract, using a syringe or a catheter, for the purpose of conception.

Intraperitoneal insemination: An artificial insemination technique in which sperm are introduced into the body cavity between the uterus and the rectum, after ovulation has been induced, for the purpose of conception.

Intrauterine device (IUD): Contraceptive device inserted through the cervix into the uterine cavity.

Intrauterine insemination: Artificial insemination technique in which sperm are deposited directly in the uterine cavity.

Karyotype: A photographic display of an individual's chromosomes that shows the number, size, and shape of each chromosome.

Laparoscopy: Direct visualization of the ovaries and the exterior of the fallopian tubes and uterus by means of a laparoscope (a long, narrow, illuminated instrument) introduced through a small surgical incision below the navel, to evaluate any abnormalities. Surgical procedures may also be performed using this method.

Laparotomy: A surgical incision through the abdominal wall, larger than that used in a laparoscopy, to allow visualization of reproductive structures for evaluation or surgery.

Liberty right: The natural right of a human being, capable of choice, to undertake an action freely and without interference, as long as it does not restrain or injure other persons.

Luteal phase defect (LPD): Failure of the endometrial lining of the uterus to develop properly after ovulation. This condition can be treated with progesterone.

Luteinizing hormone (LH): A gonadotropin that along with FSH stimulates and directs hormone and gamete production of the testes and ovaries.

Luteinizing hormone-releasing hormone (LH-RH): A hormone secreted by the hypothalamus that acts on the pituitary to promote secretions of gonadotropins that in turn direct hormone and gamete production by the ovaries and testes.

Menopause: The cessation of the menstrual cycle, which occurs when the ovary is virtually depleted of oocytes.

Menstrual cycle: The process of ovulation in which an oocyte matures each month in a follicle produced on the surface of the ovary. At ovulation, the follicle ruptures and the oocyte is released into the body cavity and enters the fallopian tube. If fertilization and implantataion do not occur, the uterine lining is sloughed off, producing menstrual flow. The normal menstrual cycle is about 28 days.

Microsurgery: Fine, delicate surgical procedures performed with the aid of a microscope or other magnifying apparatus. In cases of infertility, microsurgery is used to repair fallopian tubes in women and blockages of the reproductive tract in men.

Mycoplasma: A micro-organism similar to bacteria, but lacking a rigid cell wall. Mycoplasma is associated with reproductive tract infections.

National Survey of Family Growth: A survey conducted periodically (1976, 1982, and 1988) by the National Center for Health Statistics (part of DHHS) to collect data on fertility, family planning, and related aspects of maternal and child health.

Negligence: Failure to exercise reasonable care.

Nocturnal penile tumescence (NPT): The occurrence of erections during sleep.

Noncoital reproduction: Reproduction other than by sexual intercourse.

Oligomenorrhea: Scanty or infrequent menstruation, a problem found in about 20 percent of infertile women.

Oligospermia: Scarcity of sperm in the semen.

Oocyte: The female egg or ovum, formed in an ovary.

Ovaries: Paired female sex glands in which ova are developed and stored and the hormones estrogen and progesterone are produced.

Oviduct: Fallopian tube.

Ovulation: The discharge of an oocyte from a woman's ovary, generally around the midpoint of the menstrual cycle.

Ovulation induction: Treatment of ovulation dysfunction caused by such disorders as amenorrhea, oligomenorrhea, and LPD, using drugs that induce ovulation. These so-called fertility drugs include CC and gonadotropins. Ovulation induction is also used as part of the AI, IVF, and GIFT techniques.

Ovulation prediction kits: Over-the-counter hormone monitoring kits that employ the enzyme-linked immunosorbent assay procedure to measure the midcycle increase in LH that indicates ovulation is taking place.

Ovum (pl. ova): The female egg or oocyte, formed in an ovary.

Ovum donor: A woman who donates an ovum or ova to another woman.

Paternity suit: A legal action to determine the father of a child.

Pelvic inflammatory disease (PID): Inflammatory disease of the pelvis, often caused by an untreated STD. Bacteria that cause gonorrhea, chlamydia, or other infections can ascend from the lower genital tract through the endometrium (causing endometriosis), to the fallopian tubes (causing salpingitis), and possibly to the ovaries (causing oophritis).

Peritoneal cavity: The abdominal cavity.

Pituitary: A gland at the base of the brain that secretes a number of hormones related to fertility.

Polycystic ovarian disease (POD): A disease of the ovaries caused by malfunction of the hormonal system that results in ovaries clogged with cysts, making ovulation almost impossible. The reasons this occurs are unclear.

Post-coital test: Microscopic analysis of cervical mucus within a few hours of timed intercourse in order to observe and evaluate the interaction of sperm, semen, and cervical mucus. The oldest and most widely practiced post-coital test is the Sims-Huhner test.

Post-traumatic stress disorder (PTSD): An anxiety disorder involving the development of characteristic symptoms (including sexual dysfunction) following a psychologically traumatic event that is generally outside the range of normal human experience.

Preimplantation embryo: The mass of dividing cells of the zygote and the blastocyst that develop in the first 6 to 7 days after fertilization.

Preovulation: The first 14 days of a woman's menstrual cycle, when estrogen levels are rising before ovulation takes place.

Primary infertility: Infertility in those who have never had children.

Progesterone: A steroid hormone secreted by the ovary after ovulation; it may be used to treat LPD.

Prolactin: A hormone secreted by the pituitary that stimulates breast milk production and supports gonadal function.

Prostate gland: Male gland that supplies part of the fluid of the semen.

Reasonable care: The degree of care that under the circumstances would ordinarily be exercised or be expected from the ordinary prudent person; in a professional setting, that care ordinarily exercised or expected from the ordinary prudent professional.

Regulation: A rule issued by an administrative agency pursuant to authority granted to the agency by statute.

Retrograde ejaculation: Discharge of semen backward into the bladder, rather than out through the penis.

Retrograde menstruation: Menstruation that flows backwards through the fallopian tubes.

Salpingitis: Inflammation of the fallopian tubes, sometimes caused by PID.

Salpingostomy: A surgical attempt to recreate the normal fallopian opening and fimbria function in cases of complete occlusion of the fallopian tubes.

Secondary infertility: Infertility in those who have previously been fertile.

Semen: A fluid consisting of secretions from the male's seminal vesicles, prostate, and from the glands adjacent to the urethra. Semen carries sperm and is ejaculated during intercourse.

Semen analysis: Evaluation of the basic characteristics of sperm and semen, such as appearance, volume, liquefaction and viscosity, and sperm concentration and motility. The presence of bacterial infection and immunological disorders can also be determined by semen analysis. It is the fundamental diagnostic method used to evaluate male infertility.

Sexual dysfunction: The inability to achieve normal sexual intercourse for reasons such as impotence, premature ejaculation, and retrograde ejaculation in the man or of vaginismus in the woman.

Sexually transmitted diseases (STDs): Infectious diseases transmitted primarily by sexual contact, including syphilis, gonorrhea, chlamydia, herpes, and acquired immunodeficiency syndrome.

Specific performance: A remedy for breach of contract in which the court orders that the precise terms of the contract be fulfilled, rather than ordering that monetary damages be paid.

Sperm: The male reproductive cell, or gamete. Normal sperm have symmetrically oval heads, stout midsections, and long tapering tails.

Sperm bank: A place in which sperm are stored by cryopreservation for future use in artificial insemination.

Sperm motility: The ability of a sperm to move normally.

Sperm washing: The dilution of a semen sample with various tissue culture media in order to separate viable sperm from the other components of semen.

Spinal cord injuries: Injury to the spinal cord causes fertility problems in paraplegic and quadriplegic men, although not generally in women. Because of these conditions sperm quantity and quality may be decreased, there may be erection and ejaculation dysfunction, and infections of the reproductive tract may occur.

Statute: Legislation enacted by a legislature.

Surgically sterile: Surgically rendered unable to conceive or to carry to term by techniques including vasectomy, tubal ligation, and hysterectomy.

Surrogate gestational mother: A woman who gestates and carries to term an embryo to which she is not genetically related, with the intention of relinquishing the child at birth.

Surrogate mother: A woman who is artificially inseminated and carries an embryo to term, with the intention of relinquishing the child at birth.

Testes: Also known as the testicles, the paired male sex glands in which sperm and the steroid hormone testosterone are produced.

Testicular biopsy: The excision of a small sample of testicular tissue for microscopic evaluation to determine sperm production.

Testosterone: A steroid hormone, or androgen, produced in the testes that affects sperm production and male sex characteristics.

Tort: A private or civil wrong resulting from a breach of a legal duty that exists by virtue of society's legal expectations regarding interpersonal conduct, rather than by virtue of a contractual agreement.

Tubal ligation: The sterilization of a woman by surgical excision of a small section of each fallopian tube.

Ultrasound: The use of high-frequency sound waves focused on the body to obtain a video image of internal tissues, organs, and structures. Ultrasound is particularly useful for in utero examinations of a developing fetus, for evaluation of the development of ovarian follicles, and for the guided retrieval of oocytes for IVF and GIFT.

Unconstitutional: Conflicting with the provisions of a constitution, usually the U.S. Constitution. Statutory provisions or particular applications of a statutory provision found unconstitutional are thereby rendered void.

Uniform laws: Model laws approved by the Commissioners on Uniform Laws and proposed to all the State legislatures for their consideration. Uniform laws have no force or effect unless adopted by a State legislature. The UCC (Uniform Commercial Code) is a uniform law that has been the basis for almost all State commercial codes in the United States.

Uterine lavage: A flushing of the uterus to recover a preimplantation embryo.

Vaginismus: Involuntary contraction of the muscles around the outer third of the vagina, prohibiting penile entry.

Varicocele: An abnormal twisting or dilation of the vein that carries blood from the testes back to the heart; a varicose vein of the testis. It occurs most commonly on the left side.

Vas deferens: The convoluted duct that carries sperm from the testis to the ejaculatory duct of the penis.

Vasectomy: Sterilization of a man by surgical excision of a part of the vas deferens.

Vasography: An x-ray examination of the vas deferens by injection of dye through a small incision. X rays are taken giving an outline of the sperm transport system.

Void: Unenforceable and having no legal effect.

Voidable: A valid act that may later be rendered unenforceable and without legal effect.

Welfare right: A claim asserted by an individual that requires a corresponding response, obligation, or duty on the part of others to provide some benefit.

Zygote: A fertilized oocyte formed by the fusion of egg and sperm, containing DNA from both.

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